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Thursday
March 19, 1987

Briefings on How To Use the Federal Register—
For information on briefings in Atlanta, GA, and
Washington, DC, see announcement on the inside cover of
this issue.



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THE FEDERAL REGISTER

WHAT IT IS AND HOW TO USE IT

- FOR:** Any person who uses the **Federal Register** and Code of Federal Regulations.
- WHO:** The Office of the **Federal Register**.
- WHAT:** Free public briefings (approximately 2 1/2 hours) to present:
1. The regulatory process, with a focus on the **Federal Register** system and the public's role in the development of regulations.
 2. The relationship between the **Federal Register** and Code of Federal Regulations.
 3. The important elements of typical **Federal Register** documents.
 4. An introduction to the finding aids of the FR/CFR system.
- WHY:** To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

ATLANTA, GA

- WHEN:** March 26; at 9 am.
WHERE: L.D. Strom Auditorium, Richard B. Russell Federal Building, 75 Spring Street, SW., Atlanta, GA.
RESERVATIONS: Call the Atlanta Federal Information Center, 404-331-2170.

WASHINGTON, DC

- WHEN:** March 31; at 9 am.
WHERE: Office of the **Federal Register**, First Floor Conference Room, 1100 L Street NW., Washington, DC.
RESERVATIONS: Beverly Fayson, 202-523-3517

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

FARM CREDIT ADMINISTRATION

12 CFR Part 620

Disclosure to Shareholders; Public Hearing

AGENCY: Farm Credit Administration.
ACTION: Hearings on final regulations.

SUMMARY: The Farm Credit Administration (FCA) announces a forthcoming public hearing on its current regulations relating to problem loan disclosure requirements for directors of Farm Credit System (System) institutions and their relatives. The regulations were published as final in the Federal Register on March 13, 1986 (51 FR 8644) and amended on November 21, 1986 (51 FR 42086). The FCA Board has decided to hold a public hearing because of the continuing interest expressed to the FCA by those impacted by the regulations.

DATE: The public hearing will be held beginning at 10:30 a.m. on April 7, 1987, at the offices of the Farm Credit Administration in McLean, Virginia.

ADDRESS: Submit requests to appear and present testimony at the public hearing in writing (in triplicate) to Kenneth J. Auberger, Secretary, Farm Credit Administration Board, Farm Credit Administration, McLean, VA 22101-5090.

FOR FURTHER INFORMATION CONTACT: Kenneth J. Auberger, Secretary, Farm Credit Administration Board, Farm Credit Administration, McLean, VA 22101-5090, (703) 883-4010.

SUPPLEMENTARY INFORMATION: A public hearing will be held at the FCA offices in McLean, Virginia commencing at 10:30 a.m. on April 7, 1987 concerning the problem loan disclosure requirements applicable to directors of the Farm Credit System institutions under FCA regulations. A person who wishes to present testimony at a session

of the hearing must request that their name be placed on the calendar by 12:00 noon on April 2, 1987. Requests will be honored in the order received. The request should state the name, address and telephone number of the person wishing to testify and the general nature of the testimony which they will offer.

Formal presentations will be restricted to 5 minutes per person. In order to facilitate discussion on the record, witnesses must submit a detailed or summary statement of the text of their comments prior to the hearing. Persons will be notified by the FCA of acceptance of their request. All documents and testimony received by the FCA as part of the public hearing process will be made part of the public record and will be available for public inspection at the FCA's offices in McLean, Virginia.

The FCA notes that the hearing is to solicit the views of interested parties concerning the content of the regulations and their application to System institutions. The FCA will not accept testimony or written statements in connection with the hearing which are not confined to this subject.

Kenneth J. Auberger,

Secretary.

[FR Doc. 87-5916 Filed 3-18-87; 8:45 am]

BILLING CODE 6705-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 86-NM-28-AD; Amdt. 39-5586]

Airworthiness Directives; McDonnell Douglas Model DC-10-10, -10F, -15, -30, -30F, and KC-10A (Military) Series Airplanes, Fuselage Numbers 1 Through 412

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive, applicable to certain McDonnell Douglas Model DC-10, and KC-10A (Military) series airplanes, which requires installation of a secondary retention system for the engine core cowl doors. This amendment is prompted by incidents in which failure occurred to the engine

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core cowl door latches. This AD is necessary because improper engagement of the engine core cowl door latches, without the secondary retention system, may result in separation of the door, which in turn may cause structural damage to the airplane during flight.

EFFECTIVE DATE: April 27, 1987.

ADDRESSES: The applicable service information may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director, Publications and Training, C1-L65 (54-60). This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or at 4344 Donald Douglas Drive, Long Beach, California.

FOR FURTHER INFORMATION CONTACT:

Mr. Augusto U. Coo, Aerospace Engineer, Airframe Branch, ANM-121L, FAA, Northwest Mountain Region, Los Angeles Aircraft Certification Office, 4344 Donald Douglas Drive, Long Beach, California 90808; telephone (213) 514-6319.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include an airworthiness directive which requires installation of a secondary latch system on certain DC-10 airplanes, was published in the *Federal Register* on May 8, 1986 (51 FR 17056).

Since issuance of the proposal, there have been two more incidents of DC-10 engine core cowl door separation. The core cowl door separations have been attributed to improper engagement of the core cowl forward latch. Corrosion and wear may damage the forward latch to such an extent that it may appear to be fully engaged and in locked position but actually not properly engaged at all. When the improperly engaged core cowl door is subjected to the high-velocity fan duct air which impinges on the door's forward edge, the forward latch becomes disengaged and the door departs the airplane.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the significant comments received.

Two commenters requested that procedures such as periodic inspections and functional checks be specified instead of mandating a secondary

retention system, and that the operators should be given the opportunity to implement these procedures. The FAA does not concur. The FAA has determined that corrosion and wear, plus improper adjustment procedures, are factors that contribute to improper engagement of the latches. Even though the manufacturer, since 1972, has issued several publications relating to the core cowl door latch maintenance, such as AOL 10-310, AOL 10-1215, Service Bulletin 71-86, etc., the FAA has determined that the procedures described in those documents have not been adequate to prevent core cowl door separation.

Two commenters expressed that the proposed 12-month compliance time is too short for the time necessary to order, obtain, and install the required modification parts, and that it would result in hardship for the operators. The FAA has reconsidered the proposed compliance time, and has determined that it may be increased to 18 months without compromising safety. The final rule has been revised accordingly.

Since issuance of the NPRM, the FAA has reviewed and approved McDonnell Douglas Service Bulletin 71-142, dated September 26, 1986, which describes the installation of a secondary retention system on left and right core cowl doors. The FAA has determined that this service bulletin describes an appropriate alternate means of accomplishing the intent of this AD. Therefore, paragraph A. of the AD has been revised to specifically reference this modification and service bulletin as an optional means of accomplishing the requirements of the AD. This change has been made strictly for informational purposes. The economic impact information, below, has been revised to reflect the estimated number of manhours required by those operators who wish to accomplish the requirements of the AD in accordance with the McDonnell Douglas service bulletin.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the following rule with the changes previously noted.

It is estimated that 150 airplanes of U.S. registry will be affected by this AD, that it will take approximately 120 manhours per airplane to accomplish the required actions, and that the average labor cost will be \$40 per manhour. The kit cost per airplane is about \$2,000. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$1,020,000.

For the reasons discussed above, the FAA has determined that this regulation is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this rule will not have a significant economic effect on a substantial number of small entities because few, if any, Model DC-10 airplanes are operated by small entities. A final evaluation has been prepared for this regulation and has been placed in the docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423, 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new airworthiness directive:

McDonnell Douglas: Applies to McDonnell Douglas Model DC-10-10, -10F, -15, -30, -30F, and KC-10A (Military) airplanes, certificated in any category. Compliance required as indicated, unless previously accomplished.

To prevent structural damage to the airplanes due to engine core cowl door separation, accomplish the following:

A. Within eighteen months after the effective date of this AD, modify the engine core cowl doors by installing a secondary retention system for the engine core cowl doors in accordance with the Accomplishment Instructions of McDonnell Douglas Model DC-10 Service Bulletin 71-142, dated September 26, 1986, or later FAA-approved revision; or in accordance with data approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

B. Alternate means of compliance which provide an acceptable level of safety may be used when approved by the Manager, Los Angeles Aircraft Certification Office, FAA Northwest Mountain Region.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a base for accomplishment of modifications required by this AD.

All persons affected by this directive who have not already received the appropriate service documents from the

manufacturer may obtain copies upon request to McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director, Publications and Training, C1-L65 (54-60). These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Los Angeles Aircraft Certification Office, 4344 Donald Douglas Drive, Long Beach, California.

This Amendment becomes effective April 27, 1987.

Issued in Seattle, Washington, on March 12, 1987.

Frederick M. Isaac,

Acting Director, Northwest Mountain Region.

[FR Doc. 87-5875 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 85-ASW-17; Amdt. 39-5525]

Airworthiness Directives; Sikorsky Model S-61L, S-61N, S-61NM, S-61R, S-61A, and S61V Series Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment amends an existing airworthiness directive (AD) which requires frequent inspections of main rotor blades to detect a possible spar crack on Sikorsky S-61 series helicopters used in certain types of external cargo operations. This amendment reduces the frequency of the blade inspections for those helicopters used in Federal Aviation Regulations (FAR) Part 133 (external load) operations that conduct six or less external load lifts per flight hour. The amendment is also needed to prevent operators who conduct more than six cargo lifts per hour from operating with a cracked main rotor blade spar which could result in the loss of the helicopter.

DATE: April 13, 1987.

Compliance: As required in the body of the AD.

ADDRESSES: The applicable service bulletins (SB) and rotorcraft flight manuals (RFM) may be obtained from Sikorsky Aircraft, Division of United Technologies, 6900 Main Street, Stratford, Connecticut 06601-1381, ATTN: S-61 Commercial Product Support Department.

A copy of the pertinent sections of the above documents is contained in the Rules Docket, Docket No. 85-ASW-17, Office of the Regional Counsel.

Southwest Region, FAA, 4400 Blue Mound Road, Fort Worth, Texas 76106.

FOR FURTHER INFORMATION CONTACT: Donald F. Thompson, Airframe Branch, Boston Aircraft Certification Office, FAA, 12 New England Executive Park, Burlington, Massachusetts 01803, telephone (617) 274-7113.

SUPPLEMENTARY INFORMATION: A proposal to amend an amendment to Part 39 of the FAR which relaxes the frequency of inspections on certain Sikorsky Model S-61 helicopters was published in the *Federal Register* on September 22, 1986 (51 FR 33621). This amendment amends Amendment 39-5129 (50 FR 38506), AD 85-18-05, which currently requires frequent inspections of the main rotor blades to detect a possible spar crack and prevent in-flight separation of a blade on Sikorsky S-61 series helicopters used in certain types of external cargo operations, such as logging. After issuing Amendment 39-5129, the FAA has determined that the AD only considered the high number of turnaround occurrences typical of logging operations and the potential of rapid crack propagation rates on the main rotor blade spar. Although it was not intended, Part 133 (rotorcraft external load) operators with low turnaround occurrences are unnecessarily burdened with extra visual blade inspection method (VBIM) and in-cockpit blade inspection method (CBIM) in the AD, as presently worded. Therefore, the amendment removes these helicopters from the applicability statement and would cause the inspection of the main rotor blade spar pressure indicators (VBIM) and in-cockpit blade inspection system (CBIM) to revert to the inspection requirements of AD 74-20-07 (Rev. 5), Amendment 39-1971 (39 FR 33791), as amended by Amendments 39-1989, 39-2152, 39-2439, and 39-4895 for those Sikorsky Model S-61 series helicopters engaged in six or less external load lifts per flight hour. Interested persons have been afforded an opportunity to participate in the making of this amendment. No objections were received. Accordingly, the proposal is adopted without change.

The FAA determined that this regulation involves approximately eight helicopters engaged in nonlogging Part 133 external cargo operations, and the approximate reduced cost would be \$580 per aircraft for each 50 hours' time in service. Therefore, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact on a

substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft evaluation prepared for this action is contained in the regulatory docket. A copy of it, when filed, may be obtained by contacting the person identified under the caption "**FOR FURTHER INFORMATION CONTACT.**"

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration (FAA) amends § 39.13 of Part 39 of the FAR as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421, and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By amending Amendment 39-5129 (50 FR 38506), AD 85-18-05, by revising the applicability paragraph as follows:

Remove the phrase "are operating" and replace with "are engaged in more than six external cargo lifts per flight hour."

This amendment becomes effective on April 7, 1987.

This amendment amends Amendment 39-5129 (50 FR 38506) AD 85-18-05.

Issued in Fort Worth, Texas, on March 3, 1987.

Don P. Watson,

Acting Director, Southwest Region

[FR Doc. 87-5878 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 571

Food Additive Petition Format; Change of Mailing Address

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its food additive regulations, which provide for the submission of petitions for approval of food additives for use in animal foods and feeds. This document changes the mailing address for those petitions.

EFFECTIVE DATE: March 19, 1987.

FOR FURTHER INFORMATION CONTACT: George Graber, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4438.

SUPPLEMENTARY INFORMATION: Petitions for approval of food additives for use in animal foods and feeds under section 409(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)) are governed by 21 CFR Parts 570 to 573.

This document amends the regulations to provide that petitions submitted under 21 CFR 571.1 be directed to the Food and Drug Administration, Center for Veterinary Medicine, Director, Division of Animal Feeds (HFV-220), 5600 Fishers Lane, Rockville, MD 20857.

List of Subjects in 21 CFR Part 571

Animal feeds, Animal foods, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 571 is amended as follows:

PART 571—FOOD ADDITIVE PETITIONS

1. The authority citation for 21 CFR Part 571 continues to read as follows:

Authority: Secs. 409, 701, 52 Stat. 1055-1056 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 348, 371); 21 CFR 5.10, 5.11.

§ 571.1 [Amended]

2. Section 571.1 *Petitions* is amended in paragraph (c) in the petition format following the line "Food and Drug Administration" by removing "Bureau of Veterinary Medicine, Associate Director for Scientific Evaluation (HFV-100), Rockville, MD 20852" and inserting in its place "Center for Veterinary Medicine, Director, Division of Animal Feeds (HFV-220), 5600 Fishers Lane, Rockville, MD 20857."

Dated: March 12, 1987.

John M. Taylor,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-5932 Filed 3-18-87; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; USS BARBOUR COUNTY

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Secretary of the Navy has determined that USS BARBOUR County (List-1195) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special function as a naval tank landing ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: March 2, 1987.

FOR FURTHER INFORMATION CONTACT:
Captain P. C. Turner, JAGC, U.S. Navy
Admiralty Counsel, Office of the Judge
Advocate General Navy Department,
200 Stoval Street, Alexandria, VA
22332-2400. Telephone number: (202)
325-9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR Part 706. This amendment provides notice that the Secretary of the Navy has certified that USS BARBOUR (LST-1195) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS, Annex I, section 3(a), pertaining to the placement of the after masthead light and the horizontal distance between the forward and after masthead lights, without interfering with its special function as a Navy ship. The Secretary of the Navy has also certified that the aforementioned lights are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR Parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is

based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the ship's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (Water), Vessels.

PART 706-[AMENDED]

Accordingly, 32 CFR Part 706 is amended as follows:

11. The authority citation for 32 CFR Part 706 continues to read:

Authority: 33 U.S.C. 1605.

§ 706.2 [Amended]

1. Table Five of § 706.2 is amended by adding the following Navy ship to the list of vessels therein to indicate the certifications issued by the Secretary of the Navy:

Vessel	Number	Forward masthead light less than the required height above hull. Annex I, sec. 2(a)(i)	Aft masthead light less than 4.5 meters above toward masthead light. Annex I, sec. 2(a)(ii)	Masthead lights not over all other lights and obstructions. Annex I, sec. 2(f)	Vertical separation of masthead lights used when towing less than required by Annex I, sec. 2(a)(i)	Aft masthead lights not visible over forward light 1,000 meters ahead of ship in all normal degrees of trim. Annex I, sec. 2(b)	Forward masthead light not in forward quarter of ship. Annex I, sec. 3(a)	After masthead light less than $\frac{1}{2}$ ship's length aft of forward masthead light. Annex I, sec. 3(a)	Percentage horizontal separation attained.
USS BARBOUR COUNTY.....	LST-1195.....							X	87

Dated: March 2, 1987.

Approved.

John Lehman,

Secretary of the Navy.

[FR Doc. 87-5895 Filed 3-18-87; 8:45 am]

BILLING CODE 3810-AE-M

DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 165**

[CGD3-87-06]

Safety Zone Regulation; Delaware River

AGENCY: Coast Guard, DOT.

ACTION: Emergency rule.

SUMMARY: The Coast Guard is establishing a safety zone in the Delaware River from Kelly Point, New Jersey directly across river to the Delaware shoreline then downriver to the southern end of Pea Patch Island. The zone is needed to protect vessels and personnel from sunken debris hazards associated with the collision of the T/V SEA PRIDE II with subsequent collapse of two high voltage

transmission towers. Entry into this zone is prohibited unless authorized by the Captain of the Port.

EFFECTIVE DATE: This regulation becomes effective on 01 March 1987. It terminates on 30 March 1987 unless terminated earlier by the Captain of the Port.

FOR FURTHER INFORMATION CONTACT:

LCDR B.A. Russell, Captain of the Port Philadelphia, Port Safety Officer, (609) 456-1370.

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking was not published for this regulation and it is being made effective in less than 30 days after Federal Register publication. Publishing an NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to prevent further damage to vessels and property, and to provide safety for persons in the area.

Drafting Information

The drafters of this regulation are LCDR B.A. Russell, project officer for the Captain of the Port, and LT M.J. Gardner, project attorney, Third Coast Guard District Legal Office.

Discussion of Regulation

The incident requiring this regulation resulted from a collision of the T/V SEA PRIDE II with a high voltage transmission tower located in the Delaware River at the intersection of the Bulk Head Bar and New Castle ranges. The basis for this safety zone is to protect vessels and personnel from sunken debris which resulted from the collision and to facilitate salvage operations.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

Regulation

In consideration of the foregoing, Subpart C of Part 165 of Title 33, Code of Federal Regulations, is amended as follows:

PART 165-[AMENDED]

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1223 and 1231; 50 U.S.C. 191; 49 CFR 1.46 and 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5.

2. A new § 165.T338 is added to read as follows:

§ 165.T338 Safety Zone: Delaware River.

(a) **Location.** The following area is a safety zone: Delaware River, from Kelly Point, New Jersey directly across river to the Delaware shoreline then downriver to the southern end of Pea Patch Island.

(b) **Effective date:** This regulation becomes effective on 1 March 1987. It terminates on 30 March 1987 unless terminated earlier by the Captain of the Port.

(c) **Regulations.** (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port.

Dated: March 1, 1987.

E.K. Roe,

Captain, U.S. Coast Guard, Captain of the Port, Philadelphia.

[FR Doc. 87-5968 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[A-9-FRL-3171-6]

Delegation of Authority; New Source Performance Standards (NSPS); California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of delegation.

SUMMARY: The EPA hereby places the public on notice of its delegation of NSPS authority to the California Air Resources Board (CARB) on behalf of the San Diego County Air Pollution Control District (SDCAPCD). This action is necessary to bring the NSPS program delegations up to date with recent EPA promulgations and amendments of these categories. This action does not create any new regulatory requirements affecting the public. The effect of the delegation is to shift the primary program responsibility for the affected NSPS categories from EPA to State and local governments.

EFFECTIVE DATE: October 15, 1986.

ADDRESS: San Diego County Air Pollution Control District, 9150 Chesapeake Drive, San Diego, CA 92123.

FOR FURTHER INFORMATION CONTACT:
Julie A. Rose, State Implementation Plan Section (A-2-3), Air Programs Branch, Air Management Division, EPA, Region 9, 215 Fremont Street, San Francisco, CA 94105. Tel: (415) 974-8066, FTS 454-8066.

SUPPLEMENTARY INFORMATION: The CARB has requested authority for delegation of certain NSPS categories on behalf of the SDCAPCD. Delegation of authority was granted by a letter dated October 15, 1985 and is reproduced in its entirety as follows:

Mr. James D. Boyd,
Executive Officer, California Air Resources Board, 1102 Q Street, P.O. Box 2815, Sacramento, CA 95812.

Dear Mr. Boyd: In response to your request of September 18, 1986, I am pleased to inform you that we are delegating to your agency authority to implement and enforce certain categories of New Source Performance Standards (NSPS) on behalf of the San Diego County Air Pollution Control District (SDCAPCD). We have reviewed your request for delegation and have found the SDCAPCD's programs and procedures to be acceptable. This delegation includes authority for the following source categories:

NSPS	40 CFR part 60 subpart
Surface Coating of Metal Furniture.	EE.
Pressure Sensitive Tape and Label Surface Coating Operations.	RR.
Flexible Vinyl and Urethane Coating and Printing.	FFF.
Nonmetallic Mineral Processing Plants.	OOO.

In addition, we are redelegating the following NSPS category since the SDCAPCD's revised programs and procedures are acceptable:

NSPS	40 CFR part 60 subpart
Secondary Brass & Bronze Ingot Production Plants.	M.

The delegation of Subpart III, Petroleum Dry Cleaners will be discussed in a separate letter.

Acceptance of this delegation constitutes your agreement to follow all applicable provisions of 40 CFR Parts 60 and 61, including use of EPA's test methods and procedures. The delegation is effective upon the date of this letter unless the USEPA receives written notice from you or the District of any objections within 10 days of receipt of this letter. A notice of this delegated authority will be published in the *Federal Register* in the near future.

Sincerely,

Judith E. Ayres,
Regional Administrator.

cc: San Diego County Air Pollution Control District

With respect to the areas under the jurisdiction of the SDCAPCD, all reports,

applications, submittals, and other communications pertaining to the above listed NSPS source categories should be directed to the SDCAPCD at the address shown in the **ADDRESS** section of this notice. The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291. I certify that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act.

This notice is issued under the authority of sections 111 and 112 of the Clean Air Act, as amended (42 U.S.C. 1857, et seq.).

Dated: March 10, 1987.

John Wise,

Acting Regional Administrator.

[FR Doc. 87-5910 Filed 3-18-87; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 60

[A-9-FRL-3171-2]

Delegation of New Source Performance Standards (NSPS); State of Hawaii

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of delegation.

SUMMARY: The EPA hereby places the public on notice of its delegation of NSPS authority to the Hawaii Department of Health (HDOH). This action is necessary to bring the NSPS program delegations up to date with recent EPA promulgations and amendments of these categories. This action does not create any new regulatory requirements affecting the public. The effect of the delegation is to shift the primary program responsibility for the affected NSPS categories from EPA to State and local governments.

EFFECTIVE DATE: January 27, 1987.

FOR FURTHER INFORMATION CONTACT:
Julie A. Rose, State Implementation Plan Section (A-2-3), Air Programs Branch, Air Management Division, EPA, Region 9, 215 Fremont Street, San Francisco, CA 94105, Tel: (415) 974-8066, FTS 454-8066.

SUPPLEMENTARY INFORMATION: The HDOH has requested authority for delegation of certain NSPS categories. Delegation of authority was granted by a letter dated January 27, 1987 and is reproduced in its entirety as follows:

John Lewin, M.D.

Director of Health, Hawaii Department of Health P.O. Box 3378, Honolulu, HI 96801.

Dear Dr. Lewin: In response to your request of December 30, 1986, I am pleased to inform you that we are delegating to your agency

authority to implement and enforce one additional New Source Performance Standard (NSPS) category in 40 CFR Part 60. We have reviewed your request for delegation and have found your present programs and procedures to be acceptable.

This delegation amends the NSPS/NESHAPS agreement between the U.S. EPA and the Hawaii Department of Health dated August 15, 1983 and the amendments dated October 25, 1984, December 18, 1984, March 18, 1985, and September 30, 1986. The agreement is amended by adding authority for Subpart Db, Standards of Performance for Industrial-Commercial-Industrial Steam Generating Units and renumbering the subparagraph under paragraph No. 1, "Permits". A copy of the amended agreement is enclosed.

Acceptance of this delegation constitutes your agreement to follow all applicable provisions of 40 CFR Part 60, including use of EPA approved test methods and procedures. The delegation is effective upon the date of this letter unless the USEPA receives written notice from you of any objections within 10 days of receipt of this letter. A notice of this delegated authority will be published in the *Federal Register* in the near future.

Sincerely,

Judith E. Ayres,
Regional Administrator.

With respect to the areas under the jurisdiction of the HDOH, all reports, applications, submittals, and other communications pertaining to the above listed NSPS source categories should be directed to the HDOH at the address shown in the letter of delegation.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

I certify that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act.

This Notice is issued under the authority of section 111 of the Clean Air Act, as amended (42 U.S.C. 1857, et seq.).

Dated: March 10, 1987.

John Wise,
Acting Regional Administrator.

[FR Doc. 87-5912 Filed 3-18-87; 8:45 am]
BILLING CODE 6560-50-M

40 CFR Part 60

[A-9-FRL-3171-1]

Delegation of New Source Performance Standards (NSPS) State of Nevada

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of delegation.

SUMMARY: The EPA hereby places the public on notice of its delegation of NSPS authority to the Washoe County

District Health Department (WCDHD). This action is necessary to bring the NSPS program delegations up to date with recent EPA promulgations and amendments of these categories. This action does not create any new regulatory requirements affecting the public. The effect of the delegation is to shift the primary program responsibility for the affected NSPS categories from EPA to State and local governments.

EFFECTIVE DATE: February 24, 1987.

FOR FURTHER INFORMATION CONTACT: Julie A. Rose, State Implementation Plan Section (A-2-3), Air Programs Branch, Air Management Division, EPA, Region 9, 215 Fremont Street, San Francisco, CA 94105, Tel: (415) 974-8066, FTS 454-8066.

SUPPLEMENTARY INFORMATION: The WCDHD has requested authority for delegation of a NSPS category. Delegation of authority was granted by a letter dated February 24, 1987 and is reproduced in its entirety as follows:

Michael Ford, M.P.H.

*District Health Officer, Washoe County
District Health Department, 1001 East
Ninth Street, P.O. Box 11130, Reno, NV
89520.*

Dear Mr. Ford: In response to your request of February 9, 1987, I am pleased to inform you that we are delegating to your agency authority to implement and enforce the New Source Performance Standard (NSPS) category in 40 CFR Part 60: Subpart 000, Standards of Performance for Nonmetallic Mineral Processing Plants. We have reviewed your request for delegation and have found your present programs and procedures to be acceptable.

Your letter also requested delegation of NSPS, Subpart SSS, Magnetic Tape Manufacturing. We are unable to delegate that Subpart at this time because it has not yet been promulgated in the *Federal Register*. We will delegate Subpart SSS to your agency when promulgation has occurred.

Acceptance of this delegation constitutes your agreement to follow all applicable provisions of 40 CFR Part 60, including use of EPA approved test methods and procedures. The delegation is effective upon the date of this letter unless the USEPA receives written notice from you of any objections within 10 days of receipt of this letter. A notice of this delegated authority will be published in the *Federal Register* in the near future.

Sincerely,

Judith E. Ayres,
Regional Administrator.

With respect to the areas under the jurisdiction of the WCDHD, all reports, applications, submittals, and other communications pertaining to the above listed NSPS source category should be directed to the WCDHD at the address shown in the letter of delegation.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive

Order 12291. I certify that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act.

This Notice is issued under the authority of section 111 of the Clean Air Act, as amended (42 U.S.C. 1857, et seq.).

Dated: March 10, 1987.

John Wise,

Acting Regional Administrator.

[FR Doc. 87-5913 Filed 3-18-87; 8:45 am]
BILLING CODE 6560-50-M

40 CFR Parts 60 and 61

[A-9-FRL-3171-3]

Delegation of Authority; New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAPS); California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Authority delegation.

SUMMARY: The EPA hereby places the public on notice of its delegation of NSPS and NESHAPS authority to the California Air Resources Board (CARB) on behalf of the Ventura County Air Pollution Control District (VCAPCD). This action is necessary to bring the NSPS and NESHAPS program delegations up to date with recent EPA promulgations and amendments of these categories. This action does not create any new regulatory requirements affecting the public. The effect of the delegation is to shift the primary program responsibility for the affected NSPS and NESHAPS categories from EPA to State and local governments.

EFFECTIVE DATE: January 27, 1987.

ADDRESS: Ventura County Air Pollution Control District, 800 South Victoria Avenue, Ventura, CA 93009.

FOR FURTHER INFORMATION CONTACT: Julie A. Rose, State Implementation Plan Section (A-2-3), Air Programs Branch, Air Management Division, EPA, Region 9, 215 Fremont Street, San Francisco, CA 94105, Tel: (415) 974-8066, FTS 454-8066.

SUPPLEMENTARY INFORMATION: The CARB has requested authority for delegation of certain NSPS and NESHAPS categories on behalf of the VCAPCD. Delegation of authority was granted by a letter dated January 27, 1987, and is reproduced in its entirety as follows:

Mr. James D. Boyd,

Executive Officer, California Air Resources Board, 1102 Q Street, P.O. Box 2815, Sacramento, CA 95812

Dear Mr. Boyd: In response to your request

of January 2, 1987, I am pleased to inform you that we are delegating to your agency authority to implement and enforce certain categories of New Source Performance Standards (NSPS) on behalf of the Ventura County Air Pollution Control District (VCAPCD). We have reviewed your request for delegation and have found the VCAPCD's programs and procedures to be acceptable. This delegation includes authority for the following source categories:

NSPS	40 CFR Part 60 Subpart
Secondary Emissions from Basic Oxygen Process Steelmaking Facilities (C, after 1/20/83).	Na
Equipment leaks of VOC from Onshore Natural Gas Processing Plants.	KKK
Onshore Natural Gas Processing: SO ₂ Emissions	LLL
Nonmetallic Mineral Processing Plants	OOO
Wool Fiberglass Insulation Manufacturing	PPP

In addition, we are redelegating the following NSPS and National Emission Standards for Hazardous Air Pollutants (NESHAPS) categories since the VCAPCD's revised programs and procedures are acceptable:

NSPS	40 CFR Part 60 Subpart
General Provisions	A
Fossil Fuel Fired Steam Generators	D
Electric Utility Steam Generators	Da
Incinerators	E
Portland Cement Plants	F
Nitric Acid Plants	G
Sulfuric Acid Plants	H
Asphalt Concrete Plants	I
Petroleum Refineries	J
Storage Vessels for Petroleum Liquids	K
Petroleum Storage Vessels	Ka
Secondary Lead Smelters	L
Secondary Brass & Bronze Ingots Production Plants	M
Primary Emissions from Basic Oxygen Sewage Treatment Plants	O
Primary Copper Smelters	P
Primary Zinc Smelters	Q
Primary Lead Smelters	R
Primary Aluminum Reduction Plants	S
Phosphate Fertilizer Industry: Wet Process Phosphoric Acid Plants	T
Phosphate Fertilizer Industry: Superphosphoric Acid Plants	U
Phosphate Fertilizer Industry: Diammonium Phosphate Plants	V
Phosphate Fertilizer Industry: Triple Superphosphate Plants	W
Phosphate Fertilizer Industry: Granular Triple Superphosphate	X
Coal Preparation Plants	Y
Ferroalloy Production Facilities	Z
Iron and Steel Plants (Electric Arc Furnaces)	AA
Kraft Pulp Mills	BB
Glass Manufacturing Plants	CC
Grain Elevators	DD
Surface Coating of Metal Furniture	EE
Stationary Gas Turbines	GG
Lime Manufacturing Plants	HH
Lead-Acid Battery Manufacturing Plants	KK
Automobile & Light-Duty Truck Surface Coating Operations	MM
Phosphate Rock Plants	NN
Ammonium Sulfate	PP
Graphic Arts Industry: Publication Rotoogravure Printing	QQ
Pressure Sensitive Tape and Label Surface Coating Operations	RR
Industrial Surface Coating: Large Appliances	SS
Metal Coil Surface Coating	TT
Asphalt Processing and Asphalt Roofing Manufacturer	UU

NSPS	40 CFR Part 60 Subpart
Synthetic Organic Chemical Manufacturing Industry: Equipment Leaks of VOC	VV
Beverage Can Surface Coating	WW
Flexible Vinyl and Urethane Coating and Printing	FFF
Equipment Leaks of VOC, Petroleum Refineries and Synthetic Organic Chemical Manufacturing Industry	GGG
Synthetic Fiber Production Facilities	HHH
Petroleum Dry Cleaners	JJJ

NSPS	40 CFR Part 60 Subpart
General Provisions	A
Asbestos	B
Beryllium	C
Beryllium Rocket Motor Firing	D
Mercury	E
Vinyl Chloride	F
Equipment Leaks (Fugitive Emission Sources) of Benzene	J
Asbestos	M
Equipment Leaks (Fugitive Emission Sources)	V

Acceptance of this delegation constitutes your agreement to follow all applicable provisions of 40 CFR Parts 60 and 61, including use of EPA's test methods and procedures. The delegation is effective upon the date of this letter unless the USEPA receives written notice from your or the District of any objections within 10 days of receipt of this letter. A notice of this delegated authority will be published in the *Federal Register* in the near future.

Sincerely,

Judith E. Ayres,
Regional Administrator.

cc: Ventura County Air Pollution Control District

With respect to the areas under the jurisdiction of the VCAPCD, all reports, applications, submittals, and other communications pertaining to the above listed NSPS and NESHAPS source categories should be directed to the VCAPCD at the address shown in the ADDRESS section of this notice.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

I certify that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act.

This notice is issued under the authority of sections 111 and 112 of the Clean Air Act, as amended (42 U.S.C. 1857, et seq.).

Dated: March 10, 1987.

John Wise,
Acting Regional Administrator.

[FR Doc. 87-5911 Filed 3-18-87; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Parts 60 and 61

[A-9-FRL-3171-7]

Delegation of New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAPS); State of California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of delegation.

SUMMARY: The EPA hereby places the public on notice of its delegation of NSPS and NESHAPS authority to the California Air Resources Board (CARB) on behalf of the Kern County Air Pollution Control District (KCAPCD). This action is necessary to bring the NSPS and NESHAPS program delegations up to date with recent EPA promulgations and amendments of these categories. This action does not create any new regulatory requirements affecting the public. The effect of the delegation is to shift the primary program responsibility for the affected NSPS and NESHAPS categories from EPA to State and local governments.

EFFECTIVE DATE: December 9, 1986.

ADDRESS: Kern County Air Pollution Control District, 1601 "H" Street, Suite 150, Bakersfield, CA 93301.

FOR FURTHER INFORMATION CONTACT: Julie A. Rose, State Implementation Plan Section (A-2-3), Air Programs Branch, Air Management Division, EPA, Region 9, 215 Fremont Street, San Francisco, CA 94105, Tel: (415) 974-8066, FTS 454-8066.

SUPPLEMENTARY INFORMATION: The CARB has requested authority for delegation of certain NSPS and NESHAPS categories on behalf of the KCAPCD. Delegation of authority was granted by a letter dated December 9, 1986 and is reproduced in its entirety as follows:

Mr. James D. Boyd,
Executive Officer California Air Resources Board, 1102 Q Street, P.O. Box 2815, Sacramento, CA 95812.

Dear Mr. Boyd: In response to your request of November 13, 1986, I am pleased to inform you that we are delegating to your agency authority to implement and enforce certain categories of New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAPS) on behalf of the Kern County Air Pollution Control District (KCAPCD). We have reviewed your request for delegation and have found the KCAPCD's programs and procedures to be acceptable. This delegation includes authority for the following source categories:

NSPS	40 CFR Part 60 subpart	NSPS	40 CFR Part 60 subpart	NESHAPS	40 CFR Part 61 subpart
Secondary Emissions from Basic Oxygen Process Steel-making Facilities (C. after 1/20/83).	Na	Primary Emissions from Basic Oxygen Process Furnaces (C. after 6/11/73).	N	Asbestos.....	M
Steel Plants: Electric Arc Furnaces and Argon-Oxygen Decarburization Vessels Constructed After 8-17-83.	AAa	Sewage Treatment Plants.....	O	Equipment Leaks (Fugitive Emission Sources).V	V
Metallic Mineral Processing Plants.	LL	Primary Copper Smelters.....	P		
Pressure Sensitive Tape and Label Surface Coating Operations.	RR	Primary Zinc Smelters.....	Q		
Synthetic Organic Chemical Manufacturing Industry: Equipment Leaks of VOC.	VV	Primary Lead Smelters.....	R		
Flexible Vinyl and Urethane Coating and Printing.	FFF	Primary Aluminum Reduction Plants.	S		
Equipment Leaks of VOC, Petroleum Refineries and Synthetic Organic Chemical Manufacturing Industry.	GGG	Phosphate Fertilizer Industry: Wet Process Phosphoric Acid Plants.	T		
Synthetic Fiber Production Facilities.	HHH	Phosphate Fertilizer Industry: Superphosphoric Acid Plants.	U		
Petroleum Dry Cleaners.....	JJJ	Phosphate Fertilizer Industry: Diammonium Phosphate Plants.	V		
Equipment Leaks of VOC from Onshore Natural Gas Processing Plants.	KKK	Phosphate Fertilizer Industry: Triple Superphosphate Plants.	W		
Onshore Natural Gas Processing: SO ₂ Emissions.	LLL	Phosphate Fertilizer Industry: Granular Triple Superphosphate.	X		
Nonmetallic Mineral Processing Plants.	OOO	Coal Preparation Plants Ferro-Alloy Production Facilities.	Z		
Wool Fiberglass Insulation Manufacturing.	PPP	Iron and Steel Plants (Electric Arc Furnaces).	AA		
		Kraft Pulp Mills.....	BB		
		Glass Manufacturing Plants.....	CC		
		Grain Elevators.....	DD		
		Surface Coating of Metal Furniture.	EE		
		Stationary Gas Turbines.....	GG		
		Lime Manufacturing Plants.....	HH		
		Lead-Acid Battery Manufacturing Plants.	KK		
		Automobile & Light-Duty Truck Surface Coating Operations.	MM		
		Phosphate Rock Plants.....	NN		
		Ammonium Sulfate.....	PP		
		Graphic Arts Industry: Publication Rotogravure Printing.	CQ		
		Industrial Surface Coating: Large Appliances.	SS		
		Metal Coil Surface Coating.....	TT		
		Asphalt Processing and Asphalt Roofing Manufacture.	UU		
		Beverage Can Surface Coating	WW		

In addition, we are redelegating the following NSPS and NESHAPS categories since the KCAPCD's revised programs and procedures are acceptable:

NSPS	40 CFR Part 60 subpart	NESHAPS	40 CFR Part 61 subpart
General Provisions.....	A	General Provisions.....	A
Fossil-Fuel Fired Steam Generators.	D	Asbestos.....	B
Electric Utility Steam Generators.	Da	Beryllium.....	C
Incinerators.....	E	Beryllium Rocket Motor Firing.....	D
Portland Cement Plants.....	F	Mercury.....	E
Nitric Acid Plants.....	G	Vinyl Chloride.....	F
Sulfuric Acid Plants.....	H	Equipment Leaks (Fugitive Emission Sources) of Benzene.	J
Asphalt Concrete Plants.....	I		
Petroleum Refineries.....	J		
Storage Vessels for Petroleum Liquids.	K		
Petroleum Storage Vessels.....	Ka		
Secondary Lead Smelters.....	L		
Secondary Brass & Bronze Ingot Production Plants.	M		

EPA is not delegating Radionuclides under the Clean Air Act (NESHAPS, Subparts B, H, I, K, and W) until delegation procedures and requirements are developed.

Acceptance of this delegation constitutes your agreement to follow all applicable revisions of 40 CFR Parts 60 and 61, including use of EPA's test methods and procedures. The delegation is effective upon the date of this letter unless the USEPA receives written notice from you or the District of any objections within 10 days of receipt of this letter. A notice of this delegated authority will be published in the Federal Register in the near future.

Sincerely,

Judith E. Ayres,

Regional Administrator.

cc: Kern County Air Pollution Control District

With respect to the areas under the jurisdiction of the KCAPCD, all reports, applications, submittals, and other communications pertaining to the above listed NSPS and NESHAPS source categories should be directed to the KCAPCD at the address shown in the ADDRESS section of this notice.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

I certify that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act.

This Notice is issued under the authority of sections 111 and 112 of the Clean Air Act, as amended (42 U.S.C. 1857, et seq.).

Dated: March 10, 1987.

John Wise,

Acting Regional Administrator.

[FR Doc. 87-5909 Filed 3-18-87; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 61

[A-9-FRL-3170-9]

National Emission Standards for Hazardous Air Pollutants (NESHAPS); Nevada; Delegation of Authority

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of delegation.

SUMMARY: The EPA hereby places the public on notice of its delegation of NESHAPS authority to the Nevada Department of Conservation and Natural Resources (NDCNR). This action is necessary to bring the NESHAPS program delegations up to date with recent EPA promulgations and amendments of these categories. This action does not create any new regulatory requirements affecting the public. The effect of the delegation is to shift the primary program responsibility for the affected NESHAPS categories from EPA to State and local governments.

EFFECTIVE DATE: December 12, 1986.

FOR FURTHER INFORMATION CONTACT:

Julie A Rose, State Implementation Plan Section (A-2-3), Air Programs Branch, Air Management Division, EPA, Region 9, 215 Fremont Street, San Francisco, CA 94105, Tel: (415) 974-8066, FTS 454-8066.

SUPPLEMENTARY INFORMATION: The NDCNR has requested authority for delegation of certain NESHAPS categories. Delegation of authority was granted by a letter dated December 12, 1986 and is reproduced in its entirety as follows:

Mr. Lowell H. Shifley, Jr., P.E.,
Air Quality Officer, Division of Environmental Protection, Department of Conservation and Natural Resources, 201 South Fall Street, Carson City, NV 89710

Dear Mr. Shifley: In response to your request of November 3, 1986, I am pleased to inform you that we are delegating to your agency authority to implement and enforce the National Emission Standards for Hazardous Air Pollutants (NESHAPS) categories in 40 CFR Part 61.

NESHAPS	40 CFR Part 61 Subpart
Inorganic Arsenic Emissions from Arsenic Trioxide and Metallic Arsenic Production Facilities.	P

We have reviewed your request for delegation and have found your present programs and procedures to be acceptable.

Acceptance of this delegation constitutes your agreement to follow all applicable provisions of 40 CFR Part 61, including use of EPA approved test methods and procedures. The delegation is effective upon the date of this letter unless the USEPA receives written notice from you of any objections within 10 days of receipt of this letter. A notice of this delegated authority will be published in the *Federal Register* in the near future.

Sincerely,

Judith E. Ayres,
Regional Administrator.

With respect to the areas under the jurisdiction of the NDCNR, all reports, applications, submittals, and other communications pertaining to the above listed NESHAPS source categories should be directed to the NDCNR at the address shown in the letter of delegation.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291. I certify that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act.

This Notice is issued under the authority of section 111 of the Clean Air Act, as amended (42 U.S.C. 1857, *et seq.*).

Dated: March 10, 1987.

John Wise,
Acting Regional Administrator.

[FR Doc. 87-5914 Filed 3-18-87; 8:45 am]

BILLING CODE 6560-50-M

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 507 and 552

[Acquisition Circular AC-87-1]

Comparison of Retirement Costs Under OMB Circular A-76

AGENCY: Office of Acquisition Policy, GSA.

ACTION: Temporary regulation.

SUMMARY: This Acquisition Circular temporarily implements Office of Management and Budget (OMB) Transmittal Memorandum No. 4 which revised OMB Circular A-76 procedures for calculation and comparison of retirement costs. The intended effect is to provide guidance to GSA contracting activities pending a revision to the

NESHAPS	40 CFR Part 61 Subpart
Inorganic Arsenic Emissions from Glass Manufacturing Plants.	N

NESHAPS	40 CFR Part 61 Subpart
Inorganic Arsenic Emissions from Primary Copper Smelters.	O

General Services Administration Acquisition Regulation.

EFFECTIVE DATE: March 9, 1987.

Expiration Date: This Acquisition Circular will expire September 8, 1987, unless canceled earlier or extended.

Comment Date: On or before April 20, 1987.

ADDRESS: Comments may be submitted to Ms. Marjorie Ashby, 18th and F Sts, NW., Room 4028, Office of GSA Acquisition Policy and Regulations, Washington, DC 20405, (202) 523-3822.

FOR FURTHER INFORMATION CONTACT: Ms. Shirley Scott, Office of GSA Acquisition Policy and Regulations, Washington, DC 20405, (202) 523-4765.

SUPPLEMENTARY INFORMATION: Pursuant to section 22(d) of the Office of Federal Procurement Policy Act, as amended, a determination has been made to waive the requirement for publication of procurement procedures for public comment before the regulation takes effect. Transmittal Memorandum No. 4 to OMB Circular A-76 requires that the contractor's contributions to social security (except medicare) and any thrift/profit sharing plan be excluded from the contractor's price for cost comparison purposes. The urgent need to implement OMB's revised procedures makes advance publication impracticable. The Director, Office of Management and Budget, by memorandum dated December 14, 1984, exempted certain agency procurement regulations from Executive Order 12291. The exemption applies to this rule. The General Services Administration certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule will not have a significant impact because of the limited number of solicitations subject to the requirement (approximately 21 in the next year). The information collection requirement contained in the rule has been submitted to OMB for approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Authority: 40 U.S.C. 486(c).

In 48 CFR Chapter 5, the following Acquisition Circular is added to read as follows:

General Services Administration Acquisition Regulation Acquisition Circular (AC-87-1)

To: All GSA contracting activities.
Subject: Comparison of retirement costs under OMB Circular A-76.

1. Purpose. This Acquisition Circular temporarily implements the revised

procedures for Office of Management and Budget (OMB) Circular A-76 comparisons of retirement costs.

2. Background. On October 29, 1986, OMB issued Transmittal Memorandum No. 4 which revised OMB Circular A-76 procedures for calculation and comparison of retirement costs. The new procedure provides for the deduction of social security (except medicare) and thrift/profit sharing plan contributions from the price offered by the contractor selected for comparison with the Government's in-house bid. A solicitation provision has been developed and is being prescribed for use in order to obtain the retirement costs and substantiating documentation from contractors.

3. Effective date. March 9, 1987.

4. Expiration date. This circular expires September 8, 1987, unless canceled earlier.

5. Explanation of changes.

a. Section 507.305 is amended to designate the current text as paragraph (a) and to add paragraph (b) to read as follows:

507.305 Solicitation provisions and contract clauses.

(a) * * *

(b) The contracting officer shall insert the provision at section 552.207-71, Social Security (except Medicare) and Thrift/Profit Sharing Plan Contributions, in all solicitations issued for the purpose of comparing the costs of contractor and Government performance of work.

b. Section 507.306 is added to read as follows:

507.306 Evaluation.

(a) The social security and thrift/profit sharing plan contributions will not affect the determination of the low responsive offer and should not be included on the abstract of offers. The contributions should not be announced at the public bid opening, but should be included on the cost comparison form and made available during the public review period.

(b) Contracting officers shall request documentation verifying contributions from the low responsive responsible offeror only if the contributions will affect the outcome of the cost comparison. The documentation provided by the low offeror should not be released to other offerors.

c. Section 552.207-71 is added to read as follows:

552.207-71 Social Security (Except Medicare) and Thrift/Profit Sharing Plan Contributions.

As prescribed in section 507.305(b), insert the following provision:

Social Security (Except Medicare) and Thrift/Profit Sharing Plan Contributions

(a) To provide for consistency of comparison between Government and Contractor costs, contributions to the Social Security Fund (except medicare) and any thrift/profit sharing plan costs included in the price submitted by the offeror selected to compare costs with the Government, may be deducted from that price for purposes of comparison with the Government's in-house bid.

(b) Offerors may provide, in the space provided in paragraph (h), the estimated contributions discussed above. The estimated contributions must be limited to those costs that would be allocable to a contract awarded under this solicitation for each year of the contract period, including option years.

(c) Estimated contributions to thrift/profit sharing plans to be deducted from the offeror's price shall be limited to the historical costs incurred by the offeror in the tax year previous to the solicitation date on a per employee basis. Thrift/profit sharing plans must be recognized by the Internal Revenue Service (IRS). Cost estimates that reflect improved plans will be accepted to the extent that the historical data justify the estimates used.

(d) For purposes of this provision, a thrift/profit sharing plan is defined as:

A deferred compensation arrangement in which an employee can contribute after-tax contributions to an individual account maintained in his/her behalf which may also receive matching employer contributions at some specified rate up to a maximum. A "thrift/profit sharing plan" includes a profit sharing plan as defined by 26 CFR 1.401-1(b)(1)(ii) and a stock bonus plan as defined by 26 CFR 1.401-1(b)(1)(iii). A thrift/profit sharing plan is not a "pension plan" as defined in 26 CFR 1.401-1(b)(1)(i).

(e) Upon the request of the Contracting Officer, the low responsive offeror selected to compare costs with the Government agrees to provide, within 5 working days of the request, all documentation necessary to verify the reasonableness of the social security and the thrift/profit sharing plan cost estimates submitted. Such documentation shall include, but is not limited to, the relevant pages of the corporate IRS submission for the tax year immediately prior to the date of the request, the number of contractor employees, the number of employees in the thrift/profit sharing plan, the number of employees included in the price offered and any labor hour worksheets used to develop the social security or thrift/profit sharing plan contributions submitted with the offer.

(f) Failure to submit the estimated contributions or to provide the requested documentation supportive of the estimated contributions will not make the offer nonresponsive. Such failure will, however, negate the offeror's opportunity to have such costs deducted in whole or in part from the price offered in the cost comparison with the Government's in-house bid.

(g) Disagreements between the offeror and the Contracting Officer over the validity of estimated social security or thrift/profit sharing plan contributions, which cannot be

resolved by the offeror and the Contracting Officer, will be resolved through the General Services Administration A-76 Administrative Appeal Process, established under OMB Circular A-76 and Section 7.307, Chapter 1, Title 48, Code of Federal Regulations.

(h) Offeror social security and thrift/profit sharing plan contributions by year. The contributions indicated below will not be used in the Government's determination of either responsiveness or responsibility.

Year	Social Security contribution (excluding medicare)	Thrift/profit sharing plan contribution
1.....	\$.....	\$.....
2.....		
3.....		
4.....		
5.....		
Total		

(i) The successful commercial offer will be determined on the basis of the price offered and a determination that the low offer is responsive and the offeror responsible. The offer will then be compared with the Government bid, after the appropriate social security (except medicare) and thrift/profit sharing plan deductions have been made.
(End of provision)

Dated: March 9, 1987.

Patricia A. Szervo,
Associate Administrator for Acquisition Policy.

[FR Doc. 87-5884 Filed 3-18-87; 8:45 am]
BILLING CODE 6820-61-M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 173, 174, 175, 176, and 177

[Docket No. HM-145E, Amdt. Nos. 171-92, 173-200, 174-62, 175-40, 176-25, and 177-69]

Reportable Quantity of Hazardous Substances

AGENCY: Research and Special Programs Administration, (RSPA), DOT.

ACTION: Final rule.

SUMMARY: This document removes an obsolete hazardous substance discharge reporting requirement from the Hazardous Materials Regulations and adopts a note in place thereof that draws attention to existing reporting requirements contained in U.S. Environmental Protection Agency Regulations. This action is necessary to

remove an obsolete and misleading requirement from the regulations.

EFFECTIVE DATE: April 20, 1987.

FOR FURTHER INFORMATION CONTACT:

Thomas Charlton, Standards Division Office of Hazardous Materials Transportation, RSPA, 400 Seventh Street, SW., Washington, DC 20590, (202) 366-4488.

SUPPLEMENTARY INFORMATION: On June 23, 1986, RSPA published a notice of proposed rulemaking (NPRM) under Docket HM-145E (51 FR 22902) entitled: Reportable Quantity of Hazardous Substances. The notice proposed to amend DOT's Hazardous Materials Regulations (HMR, 49 CFR Parts 171 through 179) by incorporating into the HMR many new hazardous substances with their reportable quantities and adjusting the reportable quantities of hazardous substances already in the HMR. In addition, the NPRM proposed to change the definition of "hazardous substance", as it is defined in § 171.8 of the HMR, and to change the reporting requirement for discharges of hazardous substances found at § 171.17. Both proposals were in response to actions taken by the U.S. Environmental Protection Agency (EPA) in a final rule published in the *Federal Register* on April 4, 1985, (50 FR 13456) pursuant to that agency's authority under section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

On October 18, 1986, the President signed the Superfund Amendment and Reauthorization Act (SARA) of 1986 (Pub. L. 99-499). In amending CERCLA, Congress required, *inter alia* that within 30 days the Secretary of Transportation list and regulate all hazardous substances designated under section 101(14) of CERCLA. In response to this Congressional mandate, RSPA published a final rule on November 21, 1986, under Docket HM-145F (51 FR 42174). The rule listed and regulated all hazardous substances at the reportable quantities designated by EPA pursuant to their authorities under section 102 of CERCLA and incorporated all hazardous substances into the HMR. It dealt with most of the issues raised in Docket HM-145E with the exception of the reporting requirement at § 171.17. The amendments adopted herein deal with that issue.

Hazardous substances first appeared in the HMR in 1980. They were designated by EPA, each with a reportable quantity, in 1978 pursuant to section 311 of the Federal Water Pollution Control Act (FWPCA). While the original FWPCA substances were

later incorporated into the list of CERCLA hazardous substances, they were water pollutants, and the FWPCA required that "discharges" of these materials be reported. "Discharges" were defined in the FWPCA as spills to the waters of the United States or adjoining shorelines. EPA and the Coast Guard, who have spill response and clean up responsibility for both oil and hazardous substances under the FWPCA, published separate regulations requiring that discharges of these materials be reported to the Coast Guard's National Response Center (NRC). The Coast Guard reporting requirements are found at 33 CFR Part 153, and EPA's at 40 CFR Part 117. When RSPA placed these original hazardous substances in the § 172.101 Table in 1980, it also placed a reporting requirement for their discharge in the HMR at § 171.17 which was similar to the EPA and the Coast Guard requirements. Section 171.17 presently requires that the owner or operator of a facility (including a transport vehicle) report to the NRC any discharge of a hazardous substance into the navigable waters or upon adjoining shorelines as soon as he has knowledge of the discharge.

In addition to adding many hazardous substances to those already designated pursuant to the FWPCA, CERCLA expanded the scope of spill reporting to the biosphere (i.e., navigable waters, ground water, earth, and air). Under CERCLA, a "release" (a term which replaced "discharge") of a hazardous substance in a reportable quantity to any of these environmental media must be reported under CERCLA. With advent of CERCLA, the reporting requirement at § 171.17 has become both obsolete and misleading, since it references only spills threatening water. Section 103 of CERCLA contains specific requirements to report "releases" to the NRC. In addition, EPA published a second hazardous substance reporting regulation in 40 CFR Part 302 requiring reporting of "releases" of hazardous substances to the NRC.

In its NPRM (Docket HM-145E), RSPA proposed either to revise § 171.17 to reflect the expanded reporting media, or to remove § 171.17 from the HMR. RSPA received one comment on the proposed revisions to § 171.17 from EPA, urging that § 171.17 be retained but corrected to reflect the CERCLA requirements. No other persons commented on hazardous substances reporting. Based on a review of this issue, RSPA is removing § 171.17 and references to that section from the HMR. However, RSPA is incorporating a note drawing attention to existing EPA regulations requiring that an owner or

operator of a CERCLA-covered facility report each hazardous substance release to the NRC. RSPA has taken this action because § 171.17 duplicates rules promulgated by both EPA and Coast Guard. There is no basis to conclude another reporting requirement, using the authority of the Hazardous Materials Transportation Act (HMTA), would enhance safety or environmental protection. Indeed, it could confuse the regulated community. RSPA believes that it is better to reference EPA regulatory requirements than to attempt to duplicate them in the HMR.

Review by Sections

Section 171.15, which requires immediate reporting of certain hazardous materials spills, is revised by including a note drawing attention to EPA requirements at 40 CFR Part 302 to report releases of hazardous substances to the National Response Center.

Section 171.17 is removed and reserved.

Section 173.118a is revised by removing the reference to § 171.17 in paragraph (b)(6).

Section 174.45 is revised by removing the reference to § 171.17.

Section 175.45 is revised by removing paragraph (d) which references § 171.17.

Section 176.48 is revised by removing the reference to § 171.17 in paragraph (b).

Section 177.807 is revised by removing the reference to § 171.17.

Administrative Notices

Executive Order 12291

The RSPA has determined that the effect of this final rule will not meet the criteria specified in section 1(b) of Executive Order 12291 and is, therefore, not a major rule. This is not a significant rule under DOT regulatory procedures [44 FR 11034] and requires neither a Regulatory Impact Analysis, nor an environmental impact statement under the National Environmental Policy Act [49 U.S.C. 4321 *et seq.*]. A regulatory evaluation is available for review in the Docket.

Impact on Small Entities

Based on limited information concerning the size and nature of the entities likely to be affected, I certify this rule will not, as promulgated, have a significant economic impact on a substantial number of small entities under criteria of the Regulatory Flexibility Act.

The following list of *Federal Register* Thesaurus of Indexing Terms apply to this rulemaking:

List of Subjects**49 CFR Part 171**

Hazardous materials transportation, Definitions.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers.

49 CFR Part 174

Hazardous materials transportation, Rail carriers.

49 CFR Part 175

Hazardous materials transportation, Air carriers.

49 CFR Part 176

Hazardous materials transportation, Maritime carriers.

49 CFR Part 177

Hazardous materials transportation, Motor carriers.

In consideration of the foregoing, Parts 171, 173, 174, 175, 176, and 177 of Title 49, Code of Federal Regulations would be amended as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citation for Part 171 continues to read as follows:

Authority: 49 U.S.C. 1802, 1803, 1804, and 1808, and 49 CFR Part 1, unless otherwise noted.

2. In § 171.15, a note is added after paragraph (c), as follows:

§ 171.15 Immediate notice of certain hazardous materials incidents.

(c) * * *

Note.—Under 40 CFR 302.6 EPA requires persons in charge of facilities (including transport vehicles, vessels, and aircraft) to report any release of a hazardous substance in a quantity equal to or greater than its reportable quantity, as soon as that person has knowledge of the release, to the U.S. Coast Guard National Response Center at (toll free) 800-424-8802 or (toll) 202-267-2675.

§ 171.17 [Removed and reserved]

3. Section 171.17 is removed and reserved.

PART 173—SHIPPERS-GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

4. The authority citation for Part 173 is revised to read as follows:

Authority: 49 U.S.C. 1803, 1804, 1805, 1808; 49 CFR 1.53(e), 1.53, App. A to Part 1, 49 U.S.C. 1655, 1655(c).

5. In § 173.118a, paragraph (b)(6) is revised to read as follows:

§ 173.118a Exceptions for combustible liquids.

(b) * * *

(6) Reporting incidents as prescribed by §§ 171.15 and 171.16 of this subchapter; and

PART 174—CARRIAGE BY RAIL

6. The authority citation for Part 174 is revised to read as follows:

Authority: 49 U.S.C. 1803, 1804, 1808; 49 CFR 1.53(e), 1.53, App. A to Part 1.

7. Section 174.45 is revised to read as follows:

§ 174.45 Reporting hazardous materials incidents.

When any incident occurs during transportation in which a hazardous material is involved, a report may be required (see §§ 171.15 and 171.16 of this subchapter).

PART 175—CARRIAGE BY AIRCRAFT

8. The authority citation for Part 175 is revised to read as follows:

Authority: 49 U.S.C. 1803, 1804, 1806, 1807, 1808; 49 CFR 1.53(c), 1.53, App. A to Part 1.

9. In § 175.45, paragraph (d) is removed as follows:

§ 175.45 Reporting hazardous materials incidents.

* * * * *

(d) [Reserved]

PART 176—CARRIAGE BY VESSEL

10. The authority citation for Part 176 is revised to read as follows:

Authority: 49 U.S.C. 1803, 1804, 1805, 1808; 49 CFR 1.53, App. A to Part 1.

11. In § 176.48, paragraph (b) is revised to read as follows:

§ 176.48 Situation requiring report.

* * * * *

(b) When an incident occurs during transportation in which a hazardous material is involved, a report may be required (see §§ 171.15 and 171.16 of this subchapter).

PART 177—CARRIAGE BY PUBLIC HIGHWAY

12. The authority citation for Part 177 is revised to read as follows:

Authority: 49 U.S.C. 1803, 1804, 1808; 49 CFR 1.53(e), 1.53, App. A to Part 1.

13. Section 177.807 is revised to read as follows:

§ 177.807 Reporting hazardous materials incidents.

When an incident occurs during transportation in which a hazardous material is involved, a report may be required (see §§ 171.15 and 171.16 of this subchapter).

Issued in Washington, DC, on March 12, 1987, under authority delegated in 49 CFR 1.53.

M. Cynthia Douglass,

Administrator, Research and Special Programs Administration.

[FR Doc. 87-5901 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-60-M

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Parts 611 and 675**

[Docket No. 61225-7052]

Groundfish of the Bering Sea and Aleutian Islands

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Final rule.

SUMMARY: NOAA issues a final rule to implement Amendment 10 to the Fishery Management Plan for the Groundfish Fishery in the Bering Sea and Aleutian Islands Area (FMP). Amendment 10 contains four parts which will (1) close an area of the exclusive economic zone (EEZ) in the Bering Sea to all commercial fishing with trawl gear, set limits on incidental catches of Tanner and red king crabs and Pacific halibut in Bering Sea foreign and domestic fisheries for yellowfin sole and other flatfish, and require that these fisheries cease when the incidental catch limits are reached; (2) require weekly catch reports from catcher/processor and mothership vessels regardless of when their catch is landed; (3) provide authority to the Secretary of Commerce (Secretary) to make certain inseason changes to gear regulations, seasons, and harvest quotas, and (4) provide the Secretary with specific inseason authority to reapportion surplus amounts of groundfish within the domestic allowable harvest category. These measures are intended to respond to biological, socioeconomic, and administrative problems that have been identified by the North Pacific Fishery Management Council (Council).

In addition, NOAA is making other regulatory changes to clarify domestic reporting requirements. These additional regulatory changes are not part of

Amendment 10, but are new interpretations of existing authority in the FMP. One of these additional changes was substantially altered in response to public comment. Hence, NOAA is reproposing this one regulatory change and requesting additional public comment. The proposed rule will be published after publication of this final rule.

The regulations implementing Amendment 10 and the additional regulatory changes in the final rule are necessary for conservation and management of the groundfish resources and for the orderly conduct of the fishery.

EFFECTIVE DATES: March 16, 1987, with the following exceptions which will become effective April 16, 1987.

In § 675.2, the definition of "processing."

In § 675.5, paragraph (3) (i) and (iv);

In § 675.7, paragraph (h); and

(g). In § 675.20, paragraphs (b), (e), (f), and

The effective period of the following will expire December 31, 1988:

In § 675.2, definitions of "bycatch limitation zones 1 and 2;"

In § 675.7, paragraphs (g) and (i); and

All of § 675.21, and § 675.22.

ADDRESS: Individual copies of the amendment, the environmental assessment (EA), and the regulatory impact review/final regulatory flexibility analysis (RIR/FRA) may be obtained from the North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, Alaska 99501, 907-274-4563.

FOR FURTHER INFORMATION CONTACT: Jay J.C. Ginter (Resource Management Specialist, NMFS) 907-586-7230.

SUPPLEMENTARY INFORMATION: Domestic and foreign groundfish fisheries in the EEZ in the Bering Sea and Aleutian Islands (BSAI) area are managed in accordance with the FMP. The FMP was developed by the Council under authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act) and is implemented by regulations appearing at 50 CFR 611.93 and Part 675.

The Council approved the four parts of Amendment 10 to the FMP for submission to the Secretary at the September 24-26, 1986, meeting of the Council. The Magnuson Act provides for this amendment to take effect at the close of the 95th day after its receipt by the Secretary unless he previously notifies the Council of his disapproval, or partial disapproval, of the amendment (16 U.S.C. 1854 (b)). The NMFS received Amendment 10 on November 24, 1986, and immediately

began a review of it to determine its consistency with the Magnuson Act and other applicable law. The Secretary has determined that Amendment 10 is consistent with the Magnuson Act and other applicable law and approved Amendment 10.

A notice of the amendment's availability was published in the *Federal Register* on December 2, 1986 (51 FR 43401), and proposed implementing regulations were published on December 18, 1986 (51 FR 45349). Both notices invited public review and comment on the amendment and proposed rule through January 22, 1987. Five letters of public comment were received and considered in developing this final rule. A summary and response to all comments received is given below.

Description

A description of and reasons for each part of Amendment 10, and the technical amendment proposed by NOAA, are given in the preamble to the proposed rule. A summary follows of what is accomplished by each part of Amendment 10, and NOAA's technical change.

1. Protection of one Tanner crab species, (*Chionoecetes bairdi*), red king crab (*Paralithodes camtschatica*), and Pacific halibut (*Hippoglossus stenolepis*) in the Eastern Bering Sea.

Closed Area

An area is closed by this rule to foreign and domestic trawl fishing in that part of the EEZ north of the Alaska Peninsula, south of 58° N. latitude, west of 160° W. longitude, and east of 162° W. longitude (Area B in Figure 2). Within that area, however, the Secretary may allow domestic trawling for Pacific cod in that portion lying south of a straight line approximating the 25 fathom depth contour, provided that such fishing is conducted under a data gathering program approved by the Regional Director after consultation with the Council. The data gathering program is to provide data useful for management of the trawl fishery, the Pacific halibut, Tanner and king crab fisheries, and is to prevent overfishing of Pacific halibut, Tanner and king crab stocks in the area. All fishing with trawl gear will cease when a PSC limit of 12,000 red king crabs has been taken in that portion of the closed area.

Prohibited Species Catch (PSC) Limits

The following PSC limits established by this rule are applicable to all U.S. (domestic) vessels fishing directly for yellowfin sole and other flatfish in the specified zone:

(1) 80,000 *C. bairdi* in bycatch limitation zone (Zone 1);

(2) 135,000 red king crabs in Zone 1; and

(3) 326,000 *C. bairdi* in Zone 2.

A separate PSC limit of 64,000 *C. bairdi* is established applicable to foreign directed fisheries for yellowfin sole and other flatfish in Zones 1 and 2 combined. This rule provides for the apportionment of this PSC limit among foreign nations based on a nation's share of the total amount of yellowfin sole and other flatfish available for foreign harvest. Regardless of whether national PSC limits are fully taken, however, the Regional Director must prohibit all foreign fishing for yellowfin sole and other flatfish in both zones when the PSC limit of 64,000 *C. bairdi* is reached. This rule also defines "directed fishing" in the foreign regulations, which is identical to the definition of directed fishing preexisting in the domestic regulations.

A PSC limit of 828,000 Pacific halibut is established by this rule applicable in the entire BSAI management area to domestic vessels in directed fisheries for yellowfin sole and other flatfish and delivering to foreign processing vessels. However, reaching this PSC limit would result in closure of only Zone 1 to domestic trawling for yellowfin sole and other flatfish for delivery to foreign processing vessels.

Achieving any of these PSC limits during the fishing year will prompt the Regional Director to publish a notice in the *Federal Register* prohibiting directed fishing for yellowfin sole and other flatfish in the applicable zone for the remainder of the fishing year. Foreign directed fishing for yellowfin sole and other flatfish will not be allowed in Zone 1 after it is closed to domestic fishing due to achievement of the domestic PSC limit for red king crab. However, foreign fishing may continue in Zone 1 if Zone 1 is closed to domestic fishing due to achievement of the domestic PSC limit for *C. bairdi*.

Discretionary Authority

This rule gives the Secretary some discretion in carrying out closures due to PSC limits. The purpose of this discretionary authority is to provide some management latitude, with respect to PSC limits, in imposing restrictions on domestic fishermen in areas and under circumstances where continued fishing can be determined to have insignificant deleterious effects on either crab stock or Pacific halibut. The discretionary authority provided by this rule will allow assessment and consideration of existing conditions within domestic

fisheries before enacting a closure due to a PSC limit. Allowing continuation or resumption of domestic fishing for yellowfin sole and other flatfish in an area that would otherwise be closed due to a PSC limit will allow the domestic industry to use groundfish resources more fully. However, a thorough assessment and consideration of existing conditions within domestic fisheries and the biological and socioeconomic risks involved will be made and relevant findings published before this discretionary authority can be fully exercised. This authority does not extend to foreign fisheries.

The closure of either or both Zones 1 and 2 due to achievement of a PSC limit will not preclude either the domestic or foreign fishery from continuing to fish for yellowfin sole and other flatfish elsewhere in the BSAI management area. For domestic fisheries, there will be no PSC limits outside of Zones 1 and 2, while the BSAI area-wide PSC limits for foreign fisheries will continue to apply outside of Zones 1 and 2.

2. Revision of domestic reporting requirements for domestic catcher/processor and mothership/processor vessels

This rule revises the domestic regulations to require vessels that process fish on board to submit weekly catch or receipt reports to the Regional Director. Formerly, the regulations required such reports from vessels if they retained fish on board for longer than 14 days. Administrative and accounting problems, however, caused the Council to recommend making the weekly reports required of all vessels processing fish at sea. The weekly reports required by this rule are to cover the seven-day period of Sunday through Saturday and must be sent to the Regional Director within one week of the end of the reporting period.

To aid identification of which fishing vessels are affected by the revised weekly reporting requirement, a new definition of "processing" is added to the domestic regulations. This definition defines processing as the preparation of fish to render it suitable for human consumption, industrial uses, or long-term storage, including, but not limited to, cooking, canning, smoking, salting, drying, freezing, and rendering into meal or oil. Under this definition, any domestic fishing vessel "processing" any part of its catch or received fish on board would be required to report weekly to the Regional Director.

3. Inseason management authority

This rule provides inseason management authority for the Secretary,

through determinations to be made by the Regional Director, to adjust gear restrictions, season opening and closing dates, total allowable catch (TAC) and PSC limits. Such adjustments must be necessary to prevent overfishing or to change TACs or PSC limits which the Regional Director finds, as a result of the best available stock status information, to have been incorrectly specified.

The Regional Director is constrained, however, in his choice of management responses to prevent potential overfishing by having to select the least restrictive adjustments, from the following management measures, to achieve the purpose of the adjustment: (1) Any gear modification that would protect the species in need of conservation protection, but which would still allow fisheries to continue for other species; (2) a time/area closure which would allow fisheries for other species to continue in noncritical areas and time periods; and, (3) total closure of the management area.

The exercise of the Secretary's authority to adjust TAC or PSC limits requires a determination, based on the best available scientific information, that the biological status or condition of a stock is different from that on which the currently specified TAC or PSC limits were specified. Any adjustments to a specified TAC or PSC limit must be reasonably related to the change in stock status.

The types of information which the Regional Director must consider in determining whether stock conditions exist that require an inseason management response are described as follows, although he is not precluded from using information not described but determined to be relevant to the issue.

(A) The effect of overall fishing effort within a regulatory area;

(B) Catch per unit of effort and rate of harvest;

(C) Relative abundance of stocks within the area;

(D) The condition of the stock within all or part of a regulatory area; and

(E) Any other factors relevant to the conservation and management of groundfish species or any incidentally caught species which are designated as a prohibited species or for which a PSC limit has been specified.

Because of the variety of possible actions that can be taken under this authority, and time and procedures required to implement an inseason adjustment will depend on its complexity and its potential impacts on the fishing industry, fishery resources and the environment. Satisfying the

requirements of the Administrative Procedure Act (APA), the Regulatory Flexibility Act and Executive Order 12291 may require more notice and analysis than was originally done for this part of Amendment 10. The extent and kind of analysis necessary will be decided on a case-by-case basis. In addition, no inseason adjustment will take effect until it has been proposed in the *Federal Register* for a public comment period of thirty days, except when such a notice is impractical, unnecessary, or contrary to the public interest. If the Secretary determines that the prior comment period should be waived, he is still required to request comments for 15 days after the notice is made effective, and respond to any opposing comments by publishing in the *Federal Register* either a notice of continued effectiveness or a notice modifying or rescinding the adjustment.

4. Reapportionment within the Domestic Annual Harvest Category (DAH)

This rule provides explicit authority to carry out a long standing policy and thereby removes any ambiguity or uncertainty about reapportionments within DAH. The DAH is composed of amounts of the TAC that are apportioned to U.S. vessels working in joint ventures with foreign processing vessels (JVP) and U.S. vessels processing their catch on board or delivering it to U.S. processors. This rule specifically allows the Regional Director to reapportion, during the fishing year on specific dates, and at other times as appropriate, amounts of the TAC that are likely to remain unharvested by DAP fisheries in a fishing year to the JVP fisheries and vice versa. The Magnuson Act provides for DAP priority access to available amounts of TAC. Hence, amounts of the TAC apportioned to DAP fisheries are not limiting on those fisheries as long as amounts apportioned to JVP and foreign fisheries remain unharvested.

5. Regulatory amendment

NOAA has made certain minor technical changes to the implementing regulations approved by the Council. Section 675.5(a)(3)(iv) is changed to require catcher/processors and mothership/processors to submit a weekly catch or receipt report after checking into a fishing area under § 675.5(a)(3)(i), regardless of whether any groundfish were caught or received. This change does not implement Amendment 10, but results from interpretation of existing authority in the FMP. As such, this change can be made by the Secretary through a notice and

comment rulemaking without formal amendment of the FMP. The intent of this change is to clarify domestic reporting requirements.

Differences Between the Final and Proposed Rules

This final rule differs from the proposed Amendment 10 implementing regulations published on December 18, 1986 (51 FR 45349), in the following ways.

1. In § 611.93 (c)(2)(ii)(E)(2)(iv), the *C. bairdi* PSC limit was incorrectly specified as applying to either Zones 1 or 2. Amendment 10 requires that this PSC limit apply to the combined Zones 1 and 2. The preamble to the proposed rule correctly explained the PSC limit as specified in Amendment 10. The PSC limit provision is changed in the final rule to conform to Amendment 10.

2. The definition of "processing" at § 675.2 is changed to exclude heading and gutting fish, without additional preparation as specified, as a form of preparation covered by the definition. This change is made to exclude small longline vessel operators, who simply head, gut, and ice their catch, from the weekly reporting requirement.

3. In § 675.5, paragraphs (a) and (b) in the proposed rule are omitted from the final rule. In response to a public comment, NOAA discovered that the wording of these paragraphs in the proposed rule was flawed in several ways.

Therefore, NOAA substantially redrafted these paragraphs and will republish them as a proposed rule after publication of this final rule and additional public comment will be requested.

4. The potential economic impacts of making inseason adjustments is added to the list of factors in § 675.20 (f) that may be considered in making the required determinations listed under § 675.20(e)(2). This change is in response to a public comment (cf. Comment 5) that suggested only biological information should be considered relevant in making inseason adjustments. However, NOAA is making clear that the potential economic impact of a decision to make or not make inseason adjustments is a factor that may be considered.

Public Comments Received

Five letters of comments were received during the comment period from fishing industry representatives. An additional letter from the Council offered guidance on the exercise of the Secretary's discretionary authority under § 675.21(d). A summary of comments on Amendment 10 and the

proposed rule and a response to each comment follows. Comments on other NOAA actions are part of the administrative record but are not responded to here.

Comment 1. Data generated from the "data gathering program" required of vessels fishing in the excepted Pacific cod fishery (cf. § 675.22 (b) and (c)) should include information on the mortality rate of incidentally harvested crabs.

Response. NOAA will attempt to collect these data if possible in carrying out the prescribed "data gathering program."

Comment 2. Vessels participating in the excepted Pacific cod fishery (cf. § 675.22 (b) and (c)) should not be asked to fund more data gatherers than is necessary to collect the needed information.

Response. NOAA agrees.

Comment 3. Reference to "mutilation [of crabs] from trawl gear as it passes over the bottom" is an unjustified reference to speculative assertions presented as scientific evidence particularly without reference also to other papers on the same subject.

Response. The quote appears in the preamble to the proposed rule near the bottom of the first column on page 45350 of the December 18, 1986, issue of the *Federal Register*. The quoted phrase is part of a sentence that describes concerns expressed at the January 1986 Council meeting. This description is for historical background purposes and does not cite scientific authority. All scientific papers cited by the Council and NOAA in the process of developing this rule are part of the administrative record and have been considered by NOAA.

Comment 4. The 24-hour advance check-in and check-out requirement (cf. § 675.5 (a)(3)(i)) places a planning burden on fishermen: the required weekly catch reports should be adequate to inform NMFS when fishing starts and stops.

Response. The purpose of the check-in and check-out requirement is to provide real-time information on the disposition of catcher/processor fishing effort and to alert the Regional Director as to which vessel operators will be submitting weekly reports. However, NOAA agrees that 24-hour advance check-in notice is an unnecessary burden and has deleted the 24 hour notice requirement but retained the check-in requirement in the final rule.

Comment 5. Only *bona fide* conservation issues should be considered in exercising the inseason adjustment authority (§ 675.20 (e)). The list of data that may be considered in

making the required determinations to exercise the inseason adjustment authority (§ 675.20 (f)) is too broad; especially the last item, "any other factors relevant . . ." This part should be modified to eliminate consideration of data not relevant to conservation.

Response. Inseason biological conservation is the main purpose of the inseason adjustment authority. The exercise of this authority must be based on the best available scientific information that the known condition of a groundfish stock is different from that on which the original TAC or PSC limits were specified. In short, any inseason adjustment must be reasonably related to a change in stock status. The effect of making (or not making) an inseason adjustment, however, will have economic as well as biological consequences. It will be important to take all relevant information, biological and economic, into consideration when making a determination on how to respond to the new information. To make this point more explicit, NOAA has added "economic impacts on fishing businesses being affected" to the list of factors that may be considered.

Comment 6. Public comment should be solicited before exercising the inseason authority under § 675.20 (e).

Response. Section 675.20 (g)(1) requires the Secretary to publish any proposed inseason adjustment for public comment for a period of 30 days before it is made final.

Comment 7. There has been a considerable history of overestimation of DAP. Reassessment of DAP should be constant and reapportionments to JVP prompt.

Response. Comment noted.

Comment 8. Apportionment of the PSC limit for *C. bairdi* among foreign nations conducting directed fisheries for yellowfin sole and other flatfish is a welcome change (cf. § 611.93 (c)(2)(ii)(E)(2)(iv)): the same kind of PSC apportionment should be done also for JVP fisheries either by nation or by joint venture company.

Response. This apportionment of a PSC limit is linked to a nation's share of the total allowable level of foreign fishing. The same kind of apportionment cannot be done for JVP fisheries unless the joint venture companies were assigned individual shares of the total JVP amount. This kind of apportionment was not considered for Amendment 10 but may be proposed to the Council for a future amendment.

Comment 9. A red king crab PSC limit and imposition of a data collection requirement on the excepted Pacific cod fishery (cf. § 675.22 (b), (c) and (d)) is

unnecessary in light of recent bycatch data.

Response. The bycatch data collected from this fishery last year under provisions of an emergency rule are very useful. However, they constitute one piece of information that may or may not be representative of all Pacific cod fisheries in the excepted area in all years. Adequate conservation of red king crab and other prohibited species often depends on reliable monitoring of variable fishery and stock conditions over time.

Comment 10. Domestic access to fishing grounds should not be contingent, by regulation, on industry funded observers. Commentor opposes any regulation which directly or indirectly imposes an observer requirement, on a permanent basis, in the absence of a national policy on domestic fishing observers.

Response. The final rule under § 675.22 or any other section does not specifically require onboard observers funded by the fishing industry before entering a fishing area. Although the "data gathering program" specified at § 675.22 (b) may rely on such observers as a means of collecting data necessary for conservation and management purposes, there may be other ways of collecting these data. As implemented last year under an emergency rule, the data gathering program required fishermen to carry a "data gatherer" onboard at their expense in return for the privilege of fishing in an area that was otherwise closed to all fishermen using trawl gear. Through industry cooperation, the program worked well and benefitted all parties involved with valuable data and harvested fish. Like the emergency rule requirement last year, the final rule also is an interim measure which will expire at the end of 1988. NOAA is currently developing a general policy on the use of onboard observers on domestic fishing vessels. Until this policy is implemented, and in the particular case of excepted fishing under § 675.22, flexibility in designing the specific "data gathering program" will best serve to balance the interests of crab protection and industry access to fishery resources.

Comment 11. In authorizing continued fishing that would otherwise be prevented due to a PSC limit being reached, the Regional Director must make certain specified determinations (§ 675.21 (d)). The potential economic loss to vessels unable to continue fishing due to a PSC limit closure should be included as a consideration.

Response. The list of considerations under § 675.21 (d) is specified in Amendment 10 and cannot be changed

in the rule except by another amendment. The potential economic loss to vessel operators unable to keep fishing was considered in the determination of the PSC limits. That concern was also the reason for the discretionary authority to allow continued fishing under § 675.21 (d). However, the impact on the prohibited species is the primary consideration in exercising the discretionary authority.

Comment 12. Revision of the definition of which vessels are subject to weekly reporting requirements is a good change; it will alleviate confusion and mistakes.

Response. Comment noted.

Comment 13. The reporting requirements for at-sea landings (§ 675.5(a)(2)) are written in a way that may promote multiple reporting of catch.

Response. NOAA agrees and has changed the rule at § 675.5(a). However, because of this and other flaws found in § 675.5 (a) and (b), NOAA substantially redrafted these paragraphs and is republishing them as a new proposed rule and is requesting additional public comment. Hence, § 675.5 (a) and (b) are omitted from this final rule. In the new proposed rule, NOAA clarifies its intent that vessel operators who catch groundfish have the primary responsibility to submit fish tickets for each sale or delivery of their catch. NOAA is not requesting a fish ticket for each off-loading or transfer of fish as the original proposed rule implied. Under the new proposed rule, a fishing vessel operator who catches groundfish and also receives groundfish at sea from other fishing vessels would be obliged to submit a fish ticket for the fish he caught and a separate fish ticket for the fish he received, if requested under § 675.5(a)(1)(ii) by the one who caught the fish. Hence, multiple fish tickets reporting catch of the same fish will be avoided.

Comment 14. Why are two reports, the fish ticket and the weekly report, of fish catches necessary?

Response. The reports serve two separate purposes. The data from each report is different and the timing of its receipt is different. The information requested on the fish tickets is more detailed than that on the weekly reports. The weight estimate on the fish ticket should be more accurate than that on the weekly reports. Also, the fish tickets convey specific data on location of catch and fishing effort. In practice, fish tickets will be submitted after catches are brought to shore so the flow of fish ticket data will be irregular. In contrast, the weekly reports will provide rough estimates (hail weights) of catch volume from broad areas on a regular basis.

This regular receipt of catch data is important to monitoring the achievement of catch quotas. Finally, gross accounting errors will more easily be found and corrected by comparing the data from both reports.

Comment 15. Commentor supports the inseason adjustment authority (§ 675.20(e)) but cautions that stability in the regulatory regime is important to the developing domestic groundfish fishery, that the public participation provisions (§ 675.20(g)) are important, and that the economic impact on adversely affected fishermen be included in the decision making.

Response. Comment noted (cf. response to comments 5 and 6).

Comment 16. Regarding reapportionment between DAP and JVP, (a) the reserve system is a better way to deal with uncertainty of DAP estimates, (b) there is no opportunity for public comment prior to any reapportionment decision, and [c] the economic impact of JVP-caught fish on the market should be considered before making a reapportionment decision.

Response. The purpose of the reserve (§ 675.20 (a)(3)) is to allow for uncertainty in all of the TAC specifications. The DAP priority to harvestable amounts of fish assures that uncertainty in DAP production in any one year is usually resolved in favor of DAP harvestors. In addition, the specified amount of fish apportioned to DAP fisheries is not a limit as long as there are JVP and foreign amounts unharvested. However, in the interest of fully using all harvestable amounts of fish, reapportionment from DAP to other categories is occasionally necessary but only after careful consideration is given to the DAP processing capacity and apparent intent. NOAA intends to continue this practice as authorized by the final rule (§ 675.20 (b)(1)(ii)). Section 675.20 (b)(2) requires the Secretary to provide opportunity for public comment prior to reapportionment unless he finds good cause not to provide this opportunity. Nevertheless, no reapportionment can take effect until it is published in the *Federal Register* as a notice with a statement of the findings on which the apportionment is based. The final rule provides for not making reapportionments if doing so would have an adverse impact on the socioeconomic considerations specified in § 675.20 (a)(2)(i)(B).

Comment 17. Section 675.20 (b) prohibits retention of halibut unless authorized by the International Pacific Halibut Commission (IPHC). Retention of halibut was not an issue debated under Amendment 10. Authority of this

bycatch issue should remain with the Council.

Response. Retention of halibut is not mentioned in § 675.20 (b) but is part of § 675.20 (c) which concerns prohibited species. The definition of Pacific halibut in this section as a prohibited species is not changed by this rule and it is not subject to Amendment 10. Halibut is defined as a prohibited species in this way so that legal catches of halibut under IPHC regulations would not be construed as illegal under the BSAI groundfish regulations.

Comment 18. The Regional Director may not lawfully be required by the FMP to adopt the least restrictive management measure (cf. § 675.20 (e)(3)), because factors such as efficiency in utilization of the crab resource, as well as conservation, may indicate or dictate that a more restrictive response should be employed.

Response. The FMP can and does require the Secretary to implement the least restrictive response that solves the identified problem. Of course, in exercising this authority, the Secretary is bound by the Magnuson Act and other applicable law.

Comment 19. The crab protective measures in Amendment 10 should have been implemented by emergency rule to cover the period from the beginning of the groundfish fishing season (January 1) to the time when the final rule implementing Amendment 10 is in effect.

Response. One reason NOAA did not implement the crab protective measures by emergency rule in January is that historically, crab stocks are not in jeopardy of incidental catch by the fisheries for yellowfin sole and other flatfish until March. It was anticipated that Amendment 10 would be implemented in that month. Any incidental catch of red king or *C. bairdi* Tanner crabs before Amendment 10 was implemented would count against the respective PSC limits for those species. Given the history of the fisheries affected by these PSC limits, it was unlikely that a PSC limit would be reached prior to the expected implementation of Amendment 10 by final rule.

Comment 20. Management measures for Amendment 10 recommended to the Council were incorporated by reference in comments on the amendment and proposed rule.

Response. The commentor implies disagreement with the Council's choice of crab protective measures for inclusion in Amendment 10 since they are not the same as were recommended by the commentor. NOAA notes that the commentor's recommended measures

are part of the administrative record and assumes they were received and considered by the Council prior to its final decision to adopt Amendment 10. However, the management measures recommended by the Council as Amendment 10 to the FMP have been reviewed by NOAA and determined to be consistent with the Magnuson Act and other applicable law. Hence, Amendment 10 has been approved and is implemented by this final rule. NOAA did not review the commentor's recommended measures but suggests that they may be resubmitted to the Council for its consideration in a future amendment.

Comment 21. At its December 1986 meeting, the Council became aware of a problem that could compromise the intent of Amendment 10. It became apparent that the DAP rock sole fishery was likely to grow more rapidly than the Council had expected. The bycatch of *C. bairdi* and red king crab by this fishery could force a closure of the JVP flatfish fishery due to a PSC limit being reached earlier than expected when the PSC limits were set. The Council's Bycatch Subcommittee evaluated the situation and proposed a solution intended to provide guidelines in the use of the discretionary authority under § 675.21(d). The details of the proposal were unanimously endorsed by the Council (copies available from the Council at the above address). Briefly, the Council's recommendation requests that the Secretary use the § 675.21 (d) discretionary authority to allow either of the crab PSC limits which would close Zone 1 to flatfish trawling to be exceeded by up to 10,000 crabs to account for the amount of bycatch that is taken in the DAP rock sole fishery. DAP trawlers agreed to take one NMFS-approved observer in Zone 1 at their own expense for a period of no more than 45 days.

Response. The Secretary will plan to exercise the discretionary authority in this manner if, at that time, he can make the findings required in § 675.21 (d).

Classification

The Regional Director determined that this amendment is necessary for the conservation and management of the groundfish fishery and that it is consistent with the Magnuson Act and other applicable law.

The Council prepared an environmental assessment (EA) for this amendment. The Assistant Administrator for Fisheries concluded that there will be no significant impact on the human environment as a result of this rule. A copy of the EA may be

obtained from the Council at the address above.

The Administrator of NOAA determined that this rule is not a major rule requiring a regulatory impact analysis under Executive Order 12291. This determination is based on the regulatory impact review/final regulatory flexibility analysis (RIR/FRFA) prepared by the Council. A copy of the RIR/FRFA may be obtained from the Council at the address above.

The RIR/FRFA prepared by the Council describes the effects this rule will have on small entities. The analysis contained in the RIR/FRFA is largely the same as that contained in the RIR/IRFA, which was summarized for each of the measures in the proposed rule. You may obtain a copy of the FRFA from the Council at the address above.

This rule contains collection of information requirements subject to the Paperwork Reduction Act. The collection of information has been given interim approval by the Office of Management and Budget until March 31, 1987, under OMB Control Number 0648-0016. Comment on the continuation of the reporting requirement found in this rule should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attention: NOAA Desk Officer.

The Council determined that this rule will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal zone management program of Alaska. This determination was submitted for review by the responsible State agency under section 307 of the Coastal Zone Management Act. The State agency has agreed with this determination.

The Assistant Administrator has waived the 30-day delayed effectiveness period specified by the Administrative Procedure Act (APA) for certain portions of this final rule. These include the amended portions of § 611.93, definition of bycatch limitation zones 1 and 2 in § 675.2, paragraphs (g) and (i) in § 675.7, paragraph (c) in § 675.20, and all of §§ 675.21 and 675.22. The reason for this waiving of the APA 30-day cooling off period is to prevent delay in implementing these prohibited species protective measures. The fisheries restricted by these measures begin operation early in the year. One or more of the PSC limits may be reached and area closures thereby needed before the final rule would otherwise be in effect without waiving the APA 30-day cooling off period. Failure to implement such an area closure, if needed within the 30-day cooling off period, would be contrary to

the public interest in preventing excessive bycatch of red king crab and other species for which a prohibited species catch limit has been established.

This requirement is not being waived for other provisions of this rule since they are either already in effect under an emergency rule or are not necessary for immediate effectiveness.

List of Subjects

50 CFR Part 611

Fisheries, Foreign fishing.

50 CFR Part 675

Fisheries, Reporting and recordkeeping requirements.

Dated: March 16, 1987.

Carmen J. Blondin,

Deputy Assistant Administrator For Fisheries Resource Management, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR Parts 611 and 675 are amended as follows:

PART 611—[AMENDED]

1. The authority citation for 50 CFR Part 611 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*, and 16 U.S.C. 971 *et seq.*, 22 U.S.C. 1971 *et seq.*, and 16 U.S.C. 1361 *et seq.*

2. Section 611.93 is amended by adding new paragraphs (b)(1)(iii), (c)(2)(ii)(E)(2)(iv), and (c)(2)(ii) (F) and (G), and Figure 1 to read as follows:

§ 611.93 Bering Sea and Aleutian Islands groundfish fishery.

(b) * * *

(1) * * *

(iii) *Directed fishing.* With respect to any species, stock, or other aggregation of fish, means fishing that is intended or

can reasonably be expected to result in the catching, taking, or harvesting of quantities of such fish which amount to 20 percent or more of the total amount by weight of fish or fish products on board at any time. It will be a rebuttable presumption that, when any species, stock, or other aggregation of fish comprises 20 percent or more by weight of the catch, take, or harvest, or 20 percent or more of the total amount by weight of fish products on board at any time, such fishing was directed fishing for such fish.

- (c) * * *
- (2) * * *
- (ii) * * *
- (E) * * *
- (2) * * *

(iv) When, during the fishing year, the trawl vessels of a foreign nation conducting directed fishing for yellowfin sole and "other flatfish" in the combined Zones 1 and 2 (areas A and C in Figure 1) catch that nation's share of the PSC limit of 64,000 *C. bairdi* Tanner crabs, the Regional Director will publish a notice in the *Federal Register* prohibiting trawling by vessels of that nation for yellowfin sole and "other flatfish" in both of these areas for the remainder of the fishing year. A nation's share of this PSC limit will be calculated by multiplying 64,000 by a percent that is equivalent to that nation's portion of the total TALFF of yellowfin sole and "other flatfish." At the beginning of the fishing year, a portion of this PSC limit will not be distributed to nations, because some of the total TALFF of yellowfin sole and "other flatfish" may not yet be allocated. The undistributed portion of this PSC limit will be subsequently distributed to nations in proportion to increases in their yellowfin sole and

"other flatfish" allocations. Apportionments of this PSC limit notwithstanding, the Regional Director will publish a notice in the *Federal Register* prohibiting all foreign trawling for yellowfin sole and "other flatfish" in Zones 1 and 2 when such trawling catches the PSC limit of 64,000 *C. bairdi* Tanner crabs in the combined zones. For this purpose, Zone 1 is defined as that part of the management area south of 58° N. latitude and east of 165° W. longitude exclusive of other closed areas specified under this part (area A in Figure 1), and Zone 2 is defined as that part of the management area bounded by straight lines connecting the following coordinates in the order listed and exclusive of other closed areas specified under this part (area C in Figure 1):

North latitude	West longitude
54°30'	165°00'
58°00'	165°00'
58°00'	171°00'
60°00'	171°00'
60°00'	179°20'
59°25'	179°20'
54°30'	167°00'
54°30'	165°00'

(F) At all times in the area enclosed by straight lines connecting the following coordinates: 57°30' N. lat., 162°00' W. long.; 58°00' N. lat., 162°00' W. long.; 58°00' N. lat., 160°30'30" W. long. (area B in Figure 1).

(G) When the domestic fishery for yellowfin sole and "other flatfish" is prohibited under § 675.21(b) of this chapter, the directed fishery for yellowfin sole and "other flatfish" is prohibited in the same area specified in § 675.21(b) (Area A, Figure 1).

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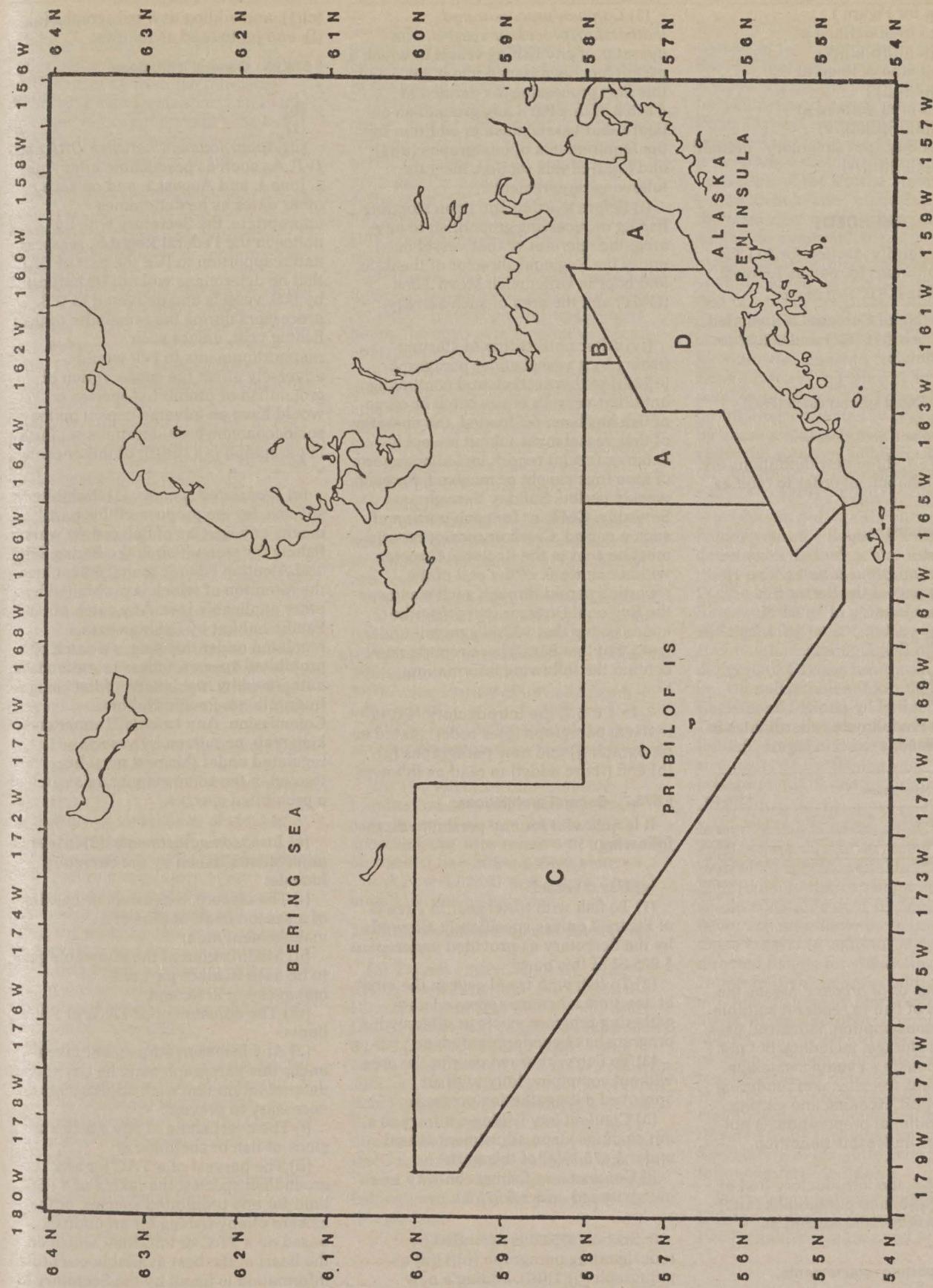


FIGURE 1

Captions for Figure 1
 A. Zone 1 area defined at § 611.93(c)(2)(ii)(E)(2)(iv)
 B. Closed area defined at § 611.93(c)(2)(ii)(F)
 C. Zone 2 area defined at § 611.93(c)(2)(ii)(E)(2)(iv)
 D. Bristol Bay "pot sanctuary" defined at § 611.93(c)(2)(ii)(A)

* * *

PART 675—[AMENDED]

3. The authority citation for 50 CFR Part 675 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

4. The Table of Contents is amended by adding new §§ 675.21 and 675.22 to read as follows:

Sec.

675.21 Prohibited species catch (PSC) limitations

675.22 Time and area closures.

5. In § 675.2, three new definitions are added in alphabetical order to read as follows:

§ 675.2. Definitions.

Bycatch limitation zone 1 (Zone 1) means that part of the Bering Sea Subarea that is south of 58°00' N. latitude and east of 165°00' W. longitude (areas A and B in Figure 2).

Bycatch limitation zone 2 (Zone 2) means that part of the Bering Sea Subarea bounded by straight lines connecting the following coordinates in the order listed (area C in Figure 2):

North latitude	West longitude
54°30'	165°00'
58°00'	165°00'
58°00'	171°00'
60°00'	171°00'
60°00'	179°20'
59°25'	179°20'
54°30'	167°00'
54°30'	165°00'

Processing, or to process, means the preparation of fish to render it suitable for human consumption, industrial uses, or longterm storage, including, but not limited to, cooking, canning, smoking, salting, drying, freezing, and rendering into meal or oil. Heading and gutting, without additional preparation, is not "processing" under this definition.

6. In § 675.5, the introductory text of paragraph (a)(3) and paragraphs (a)(3)(i) and (iv) are revised to read as follows:

§ 675.5 Reporting requirements.

(a) *

(3) *Catcher/processor and mothership/processor vessels.* The operator of any fishing vessel to which a permit has been issued under § 675.4 of this Part processing (as defined in § 675.2 of this Part) any groundfish on board that vessel must, in addition to the requirements of paragraphs (a)(1) and (a)(2) of this section, meet the following requirements:

(i) Before starting and upon stopping fishing or receiving groundfish in any area, the operator of that vessel must notify the Regional Director of the date and hour in Greenwich Mean Time (GMT) and the area of such activity.

* * *

(iv) After notification of starting fishing by a vessel under paragraph (a)(3)(i) of this section, and continuing until that vessel's entire catch or cargo of fish has been off-loaded, the operator of that vessel must submit a weekly catch or receipt report, including reports of zero tons caught or received, for each weekly period, Sunday through Saturday, GMT, or for each portion of such a period. Catch or receipt reports must be sent to the Regional Director within one week of the end of the reporting period through such means as the Regional Director will prescribe upon issuing that vessel's permit under § 675.4 of this Part. These reports must contain the following information:

* * *

7. In § 675.7, the introductory text is revised, paragraph (g) is redesignated as paragraph (j) and new paragraphs (g), (h) and (i) are added to read as follows:

§ 675.7 General prohibitions.

It is unlawful for any person to do the following:

* * *

(g) *Use a vessel:*

(1) To fish with trawl gear in Area B of Figure 2 unless specifically allowed by the Secretary as provided under § 675.22 of this part;

(2) To fish with trawl gear in the area at any time when no approved data gathering program exists or after such a program has been terminated; or

(3) To fish with trawl gear in the area without complying fully with an approved data gathering program;

(h) Conduct any fishing contrary to a notice of inseason adjustment issued under § 675.20(e) of this part;

(i) Conduct any fishing contrary to a notice issued under § 675.21; or

* * *

8. Section 675.20 is amended by redesignating paragraph (b)(1)(ii) as paragraph (b)(1)(iii), adding a new paragraph (b)(1)(ii), revising paragraph

(c)(1), and adding new paragraphs (e), (f), and (g) to read as follows:

§ 675.20 General limitations.

(b) *

(1) *

(ii) *Apportionment between DAP and JVP.* As soon as practicable after April 1, June 1, and August 1, and on such other dates as he determines appropriate, the Secretary will, by notice in the *Federal Register*, reassess and reapportion to JVP the part of DAP that he determines will not be harvested by U.S. vessels and delivered to U.S. processors during the remainder of the fishing year, unless such reapportionments to JVP would adversely affect the conservation of groundfish or prohibited species or would have an adverse impact on the socioeconomic considerations set forth in paragraph (a)(2)(i)(B) of this section.

* * *

(c) *Prohibited species.* (1) *Prohibited species,* for the purpose of this part, means any species of fish caught while fishing for groundfish in the Bering Sea and Aleutian Islands management area, the retention of which is prohibited by other applicable law. Any catch of Pacific halibut by fishing vessels regulated under this part is a catch of a prohibited species, unless retention is authorized by regulations of the International Pacific Halibut Commission. Any catch of Tanner crab, king crab, or salmon by vessels regulated under this part must be treated in the same manner as a catch of a prohibited species.

* * *

(e) *Inseason adjustments.* (1) *Inseason adjustments issued by the Secretary include:*

(i) The closure, extension, or opening of a season in all or part of a management area;

(ii) Modification of the allowable gear to be used in all or part of a management area; and

(iii) The adjustment of TACs or PSC limits.

(2) Any inseason adjustment taken under this paragraph must be based on a determination that such adjustments are necessary to prevent:

(i) The overfishing of any species or stock of fish or shellfish; or

(ii) The harvest of a TAC for any groundfish species, the taking of a PSC limit for any prohibited species, or the closure of any fishing for groundfish based on a TAC or PSC limit which on the basis of the best available scientific information is found by the Secretary to be incorrectly specified.

(3) The selection of the appropriate inseason management adjustments under paragraph (3)(1) (i) or (ii) of this section must be from the following authorized management measures and be based on an adjustment selected which is the least restrictive necessary to achieve the purpose of the adjustment:

(i) Any gear modification that would protect the species in need of conservation protection, but which would allow fisheries to continue for other species; or

(ii) A time-area closure which would allow fisheries for other species to continue in noncritical areas and time periods; or

(iii) Closure of a management area to all groundfish fishing for the remainder of the fishing year.

(4) The adjustment of a TAC or PSC limit for any species under paragraph (e)(1)(iii) of this section must be based on the best available scientific information concerning the biological stock status of the species in question and on the Regional Director's determination that the currently specified TAC or PSC limit is incorrect. Any adjustment to a TAC or PSC limit must be reasonably related to the change in biological stock status.

(f) Data. All information relevant to one or more of the following factors may be considered in making the required determinations under paragraph (e)(2) of this section:

(1) The effect of overall fishing effort within a regulatory area;

(2) Catch per unit of effort and rate of harvest;

(3) Relative abundance of stocks within the area;

(4) The condition of the stock within all or part of a regulatory area;

(5) Economic impacts on fishing businesses being affected; and

(6) Any other factors relevant to the conservation and management of groundfish species or any incidentally-caught species which are designated as a prohibited species or for which a PSC limit has been specified.

(g) Procedure. (1) No inseason adjustment issued under paragraph (e) of this section may take effect until:

(i) The Secretary has filed the proposed adjustment with the Office of the Federal Register for public inspection; and

(ii) The Secretary has published the proposed adjustment for public comment for a period of thirty (30) days before it is made final, unless the

Secretary finds for good cause that such notice and public comment is impracticable, unnecessary or contrary to the public interest.

(2) If the Secretary decides, for good cause, that an adjustment is to be made without affording a prior opportunity for public comment, public comments on the necessity for, and extent of, the adjustment will be received by the Regional Director for a period of fifteen (15) days after the effective date of the notice.

(3) During any such 15-day period, the Regional Director will make available for public inspection, during business hours, the aggregate data on which an adjustment was based.

(4) If written comments are received during any such 15-day period which oppose or protest an inseason adjustment issued under this section, the Secretary will reconsider the necessity for the adjustment and, as soon as practicable after that reconsideration, will either:

(i) Publish in the **Federal Register** a notice of continued effectiveness of the adjustment, responding to comments received; or

(ii) Modify or rescind the adjustment.

(5) Notices of inseason adjustments issued by the Secretary under this paragraph (g) must include the following information:

(i) A description of the management adjustment;

(ii) The reasons for the adjustment and the determinations required by this part; and

(iii) The effective date and any termination date of the management adjustment. If no termination date is specified, the adjustment will terminate on the last day of the fishing year.

9. A new § 675.21 and Figure 2 are added to read as follows:

§ 675.21 Prohibited species catch (PSC) limitations.

(a) Tanner crab (*C. bairdi*). (1) If, during the fishing year, the Regional Director determines that vessels of the United States will catch the PSC limit of 80,000 *C. bairdi* Tanner crabs while conducting directed fishing for yellowfin sole and "other flatfish" in Zone 1 (area A in Figure 2), he will publish a notice in the **Federal Register** prohibiting a directed fishery in Zone 1 by vessels of the United States for yellowfin sole and "other flatfish" for the remainder of the fishing year, subject to paragraph (d) of this section.

(2) If, during the fishing year, the

Regional Director determines that vessels of the United States will catch the PSC limit of 326,000 *C. bairdi* Tanner crabs while conducting directed fishing for yellowfin sole and "other flatfish" in Zone 2 (area C in Figure 2), he will publish a notice in the **Federal Register** prohibiting a directed fishery in Zone 2 by vessels of the United States for yellowfin sole and "other flatfish" for the remainder of the fishing year, subject to paragraph (d) of this section.

(b) Red king crab. If, during the fishing year, the Regional Director determines that vessels of the United States will catch the PSC limit of 135,000 red king crabs while conducting directed fishing for yellowfin sole and "other flatfish" in Zone 1 (area A in Figure 2), he will publish a notice in the **Federal Register** prohibiting a directed fishery in Zone 1 by vessels of the United States for yellowfin sole and "other flatfish" for the remainder of the fishing year, subject to paragraph (d) of this section.

(c) *Pacific halibut*. If, during the fishing year, the Regional Director determines that vessels of the United States will catch the PSC limit of 828,000 Pacific halibut while conducting directed fishing for yellowfin sole and "other flatfish" in the Bering Sea and Aleutian Islands management area for delivery to floating foreign processors, he will publish a notice in the **Federal Register** prohibiting directed fishing in Zone 1 for yellowfin sole and "other flatfish" by such vessels for the remainder of the fishing year, subject to paragraph (d) of this section.

(d) When the fishing vessels of the United States to which a PSC limit applies have caught an amount of prohibited species equal to that PSC limit (but less than an amount which would constitute over fishing), the Secretary may allow some or all of those vessels to continue or resume directed fishing for yellowfin sole and "other flatfish" under conditions which will limit fishing by permissible gear, areas, times, and other appropriate factors, and subject to other provisions of this part. Such other factors may include delivery of a vessel's catch to U.S. fish processors. In authorizing and conditioning such continued or resumed directed fishing by those vessels, the Secretary will take into account the following considerations:

(1) A determination by the Regional Director of the risk of biological harm to Pacific halibut, Tanner and king crab

stocks and of socioeconomic harm to authorized halibut and crab users posed by authorizing continued or resumed directed fishing for yellowfin sole and "other flatfish":

- (2) A determination by the Regional Director of the extent of incidental catches of Pacific halibut, Tanner and king crabs in specific areas;
- (3) A determination by the Regional Director of the accuracy of the estimates of incidental catches of Pacific halibut, Tanner and king crabs;
- (4) A determination by the Regional Director that adherence to the prescribed conditions can be assured in light of available enforcement resources; and
- (5) A determination by the Regional Director that continued or resumed directed fishing for yellowfin sole and "other flatfish" will not lead to overfishing of prohibited species.

BILLING CODE 3510-22-M

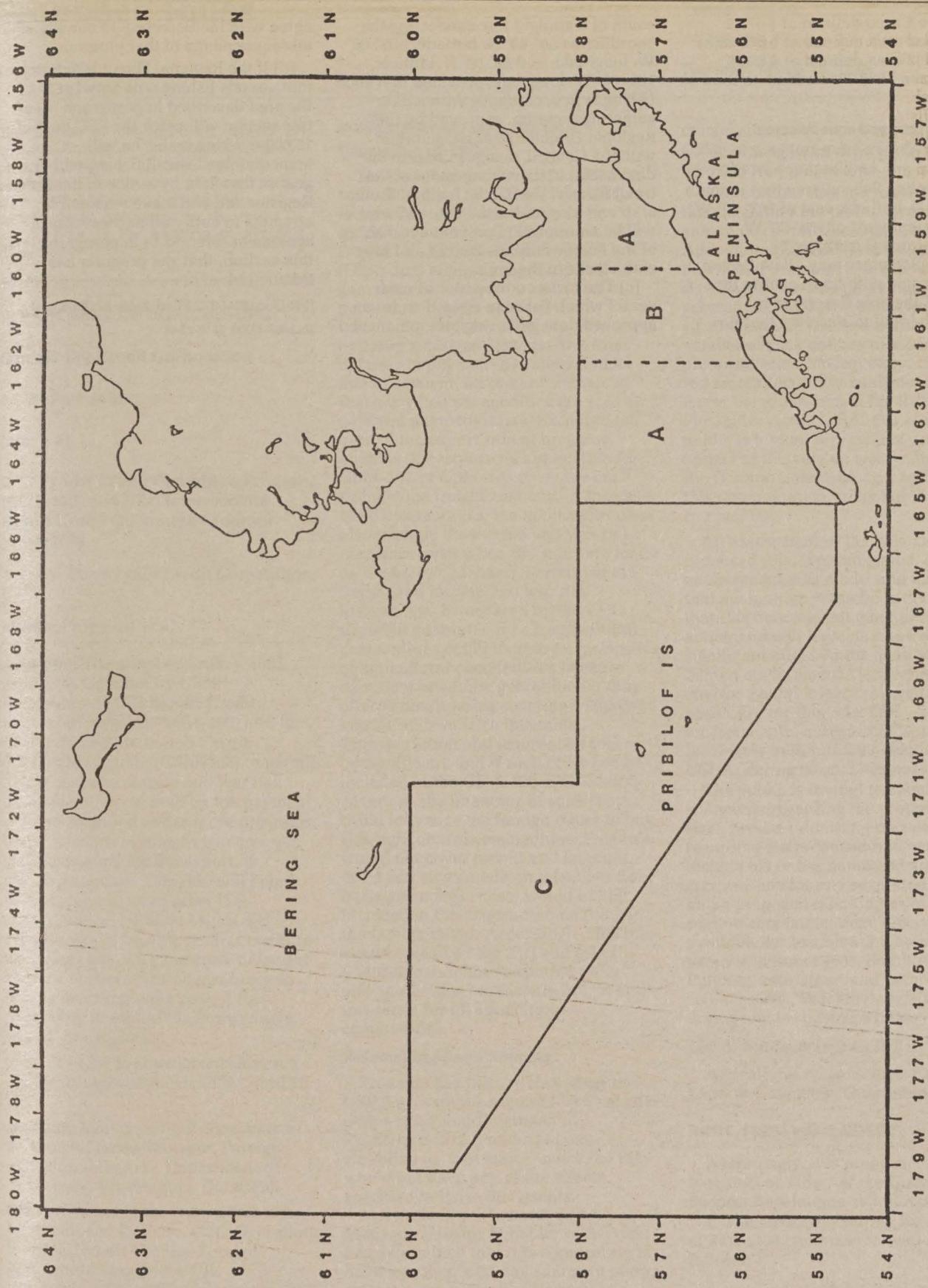


FIGURE 2

- A. Zone 1 area defined at § 675.2
- B. Closed area defined at § 675.22(a)
- C. Zone 2 area defined at § 675.2
- 10. A new § 675.22 is added, to read as follows:

§ 675.22 Time and area closures.

(a) No fishing with trawl gear is allowed at any time in that part of Zone 1 in the Bering Sea subarea that is south of 58° 00' N. latitude, east of 162° 00' W. longitude and west of 160° 00' W. longitude (area B in Figure 2).

(b) The Secretary may allow fishing for Pacific cod with trawl gear in that portion of the area described in paragraph (a) of this section that lies

south of a straight line connecting the coordinates 56° 43' N. latitude, 160° 00' W. longitude, and 56° 00' N. latitude, 162° 00' W. longitude, provided that such fishing is in accordance with a data-gathering program, approved by the Regional Director after consultation with the Council, designed to provide data useful in the management of the trawl fishery, the Pacific halibut, Tanner crab and king crab fisheries, and which will be monitored to prevent overfishing of the Pacific halibut, Tanner and king crab stocks in the area.

(c) The owner or operator of each vessel which fishes in Area B under an approved data gathering program must

agree with the Secretary to comply with all requirements of that program.

(d) If the Regional Director determines that vessels fishing with trawl gear in the area described in paragraph (a) of this section will catch the PSC limit of 12,000 red king crabs, he will immediately close all fishing with trawl gear in that area by notice in the **Federal Register** and will make reasonable attempts to notify all parties to each agreement referred to in paragraph (c) of this section, that the program has terminated.

[FR Doc. 87-5972 Filed 3-16-87; 5:06 pm]

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Proposed Rules

Federal Register

Vol. 52, No. 53

Thursday, March 19, 1987

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1493

[AMDT. 3]

CCC Export Credit Guarantee Program (GSM-102) and CCC Intermediate Export Credit Guarantee Program (GSM-103)

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Commodity Credit Corporation (CCC) Export Credit Guarantee Program (GSM-102) and the CCC Intermediate Export Credit Guarantee Program (GSM-103) to permit freight cost and marine and war risk insurance to be covered by the payment guarantees issued under these programs. Under the current rule, freight cost can only be covered for the export of breeding animals. This rule will help promote the export of other U.S. agricultural commodities since a U.S. exporter would be able to offer credit to the foreign buyer for the costs of freight and marine and war risk insurance as well as the commodity cost, if the commodity is sold to the foreign buyer on c.&f. or c.i.f. basis.

DATE: In order to assure consideration comments must be received by April 20, 1987.

ADDRESS: Mail or deliver comments to the General Sales Manager, Foreign Agricultural Service, Department of Agriculture, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT:
L.T. McElvain, Director, CCC Operations Division, Export Credits, Foreign Agricultural Service, USDA, Washington, DC 20250, Telephone: (202) 447-6225.

SUPPLEMENTARY INFORMATION:

Discussion of Rule

The current provisions of 7 CFR Part 1493, Subpart A, containing the CCC Export Credit Guarantee Program (GSM-102) and the CCC Intermediate Export Credit Guarantee Program (GSM-103) regulations provide for guarantee coverage of a specified portion of the port value of the commodity to protect the exporter or the exporter's assignee against loss from defaults in payment by foreign banks due to commercial or noncommercial reasons when commodities are sold on deferred payment terms. Except in the case of the export sale of breeding animals, the exporter's application for GSM-102 or GSM-103 coverage must exclude the freight cost and, in the case of all commodities, the application must also exclude the marine and war risk insurance even when the sales are made on a c.&f. or c.i.f. basis. Permitting the freight and marine and war risk insurance to be covered by the CCC payment guarantee for all agricultural commodities could increase export sales of agricultural commodities because exporters would be guaranteed if they offered credit terms covering freight and marine and war risk insurance. Transportation and insurance costs can be significant, and if such costs can be included in the GSM-102 or GSM-103 coverage, the financing of such costs could influence the foreign buyer to buy U.S. agricultural commodities. This rule would not cover freight and insurance on export sales made on a f.o.b. or f.a.s. basis since these costs would not be included in the exporter's sale price to the foreign buyer. Accordingly, this rule would amend § 1493.2 (f) and (o) of § 1493.2 to redefine "exported value" and "port value" to include freight and insurance for all agricultural commodities.

Rulemaking Requirements

This rule has been reviewed under USDA procedures required by Executive Order 12291 and Departmental Regulation 1512-1 and has been classified as "not major" since the rule would not have any of the effects specified in those documents.

Melvin E. Sims, General Sales Manager, Foreign Agricultural Service, has determined that it is appropriate to have less than a 60-day comment period on this proposed action because a timely adoption of the final rule is

crucial since there is an urgent need to encourage export sales of U.S. agricultural commodities.

To the extent that the provisions of the Regulatory Flexibility Act apply, if any, the General Sales Manager, Foreign Agricultural Service (FAS), certifies that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities since there will not be a substantial number of such entities affected by this proposed rule. Consequently, no regulatory flexibility analysis is required under the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The public is invited to comment on the impact of this rule on small entities, and the General Sales Manager will review this determination in light of those comments.

An assessment of the impact of this proposed rule, if promulgated, on the environment was made, and based on that evaluation, it has been determined that this action is not a major federal action and will have no foreseeable significant effect on the quality of the human environment. Consequently, no environmental impact statement is necessary for this rule. The environmental assessment is available for review in Room 4503, South Building, USDA, during normal business hours.

The public is invited to submit written comments regarding the proposed rule. Each person submitting comments regarding the proposed rule must include his or her name and address and give reasons for any suggested changes in the proposed rule. Copies of all written communications received will be available for examination by interested persons in Room 4503, South Agriculture Building, 14th Street and Independence Avenue, SW., Washington, DC 20250, during regular business hours.

List of Subjects in 7 CFR Part 1493

Agricultural commodities, Credit, Exports, Financing, Guarantees.

PART 1493—[AMENDED]

Accordingly, it is proposed to amend Part 1493 of Title 7 of the Code of Federal Regulations as follows:

1. The authority citation for Subpart A of Part 1493 continues to read as follows:

Authority: Sec. 5(f), Pub. L. 80-89, 62 Stat. 1072, as amended by sec. 405(a), Pub. L. 98-

623, 98 Stat. 3409 (15 U.S.C. 714c(f)); sec. 4(b), Pub. L. 89-808, 80 Stat. 1537, as amended by sec. 101, Pub. L. 95-501, 92 Stat. 1685 and sec. 1131, Pub. L. 99-198, 99 Stat. 1486 (7 U.S.C. 1707a(b)); 5 U.S.C. 301.

2. Section 1493.2 is amended by revising paragraphs (f) and (o) to read as follows:

§ 1493.2 Definition of terms.

(f) "Exported value" means the value of the commodity exported under the payment guarantee, basis f.a.s. or f.o.b. point of export, except that "exported value" may, upon approval by CCC, include freight costs and marine and war risk insurance for the commodity if the commodity is sold on c.f.& or c.i.f. basis.

(o) "Port value" means the total value of the export credit sale, less any discounts or allowances, basis f.a.s. or f.o.b. at U.S. points of export. Port value may, upon approval by CCC, include freight cost and marine and war risk insurance for the commodity if the export credit sale is made basis c.f.& or c.i.f., less any discounts or allowances. Such values shall include the amount of the upward loading tolerance, if any, as provided for by the export credit sales contract.

Dated: February 27, 1987.

Melvin E. Sims,

General Sales Manager and Associate Administrator, FAS, and Vice President, Commodity Credit Corporation.

[FR Doc. 87-5970 Filed 3-18-87; 8:45 am]

BILLING CODE 3410-10-M

Farmers Home Administration

7 CFR Parts 1930, 1944, and 1965

Revision of Procedures Regarding Prepayment of Multifamily Housing Loans

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Farmers Home Administration (FmHA) proposes to revised its regulations regarding its rural rental housing (RRH) and labor housing (LH) programs. The action is being taken to alleviate the problems caused by the unexpected displacement of tenants from projects after the FmHA loans are prepaid. In addition, servicing actions which subject borrowers to prepayment restrictions are being enumerated and more completely defined. These changes will provide tenants with sufficient time

to make relocation plans when a project owner prepays.

DATE: Comments must be submitted on or before April 20, 1987.

ADDRESSES: Submit written comments in duplicate to the Office of the Chief, Directives and Forms Management Branch, FmHA, Room 6346, South Agriculture Building, Washington, DC 20250. All written comments made pursuant to this notice will be available for public inspection during regular work hours at the above address. The collection of information requirements contained in this rule have been submitted to OMB for review under section 3504(h) of the Paperwork Reduction Act of 1980. Submit any comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Farmers Home Administration, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Arlene Halfon, Senior Loan Specialist, Multiple Housing Servicing and Property Management Division, FmHA, Room 5329, South Agriculture Building, Washington, DC 20250, telephone (202) 447-3187.

SUPPLEMENTARY INFORMATION: This proposed rule has been reviewed under USDA procedures established in Departmental Regulation 1512-1 which implements Executive Order 12291 and has been determined to be "nonmajor". It will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions or significant adverse effects on competition, employment, investment, productivity, innovations, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This document has been reviewed in accordance with 7 CFR Part 1940, Subpart G, "Environmental Program." It is the determination of FmHA that this proposed action does not constitute a major Federal action significantly affecting the quality of the human environment and in accordance with the National Environmental Policy Act of 1969, Pub. L. 91-190, an Environmental Impact Statement is not required.

This program/activity is listed in the Catalog of Federal Domestic Assistance under Nos. 10.427, Rural Rental Assistance Payments (Rental Assistance); 10.415, Rural Rental Housing Loans; 10.405, Farm Labor Housing Loans and Grants. For the reasons set forth in the Final Rule

related Notice(s) to 7 CFR Part 3015, Subpart V, this program/activity is included in the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

In compliance with the Regulatory Flexibility Act (Pub. L. 96-354), Mr. Vance Clark, Administrator of the Farmers Home Administration (FmHA) has determined that this section will not have a significant economic impact on a substantial number of small entities because only a few hundred borrowers will likely attempt to prepay annually.

A thirty-day comment period is being used due to the emergency nature of the problem to be alleviated. Fifty-one percent of FmHA projects and 44% of the FmHA units nationwide are eligible to prepay. Congressional hearings were held before the Subcommittee on Housing and Community Development, House Committee on Banking, Finance and Urban Affairs on September 30, 1986, on the issue of tenant displacement problems. Under the Continuing Appropriations Resolution, Pub. L. 99-500, FmHA cannot accept prepayments on RHH loans until June 30, 1987. In order to afford protection to tenants after that date, it is necessary to have these regulations in place by then. The Agency did not wish to publish this as a final rule on an emergency basis as it was felt the public, including tenants and the housing industry should have the opportunity to provide comments. We are, therefore, using the thirty days comment period on an emergency basis under 42 U.S.C. 1490 n.

The major changes and additions in this proposed rule are as follows:

1. The impact of tenant displacement will be partially alleviated by:

a. Transferring rental assistance (RA) to FmHA-financed projects to which displaced tenants receiving RA are moving, and giving these displaced tenants priority for the receipt of RA (paragraph XV B 3 Exhibit E of Subpart C of Part 1930-C).

b. Extending to six months the period in which borrowers must notify FmHA, and FmHA must notify tenants of a pending prepayment §§ 1965.90(a)(2)(i) and 1965.90(d)(1) of Subpart B of Part 1965).

c. Requiring that all leases at FmHA RRH projects be effective for a one-year period, with renewal after notification of intent to prepay allowed for a minimum term ending at the time of prepayment, and that no rent increases due to prepayment may take place prior to the expiration of the lease (paragraph VIII A and VIII C of Exhibit B of Subpart C of Part 1930).

d. Extending the period of time that tenants can apply for and sixty days in which tenants can use their letter of priority to other FmHA financed projects (§ 1965.90 (d)(1)(iv) and (d)(1)(v) of Subpart B of Part 1965).

2. The list of servicing actions which subject borrowers to prepayment penalties (transfers and assumptions on same or new terms except to ineligible borrowers and reamortizations (§ 1965.90 (b)(1) of Subpart B of Part 1965) will be more clearly enumerated.

3. The statement that tenants have a right to enforce the restrictive-use provisions will be added to the restrictive-use clause language (§ 1965.90(b)(2)(i) of Subpart B of Part 1965).

4. Each servicing action which subjects a borrower to prepayment restrictions will be stated in the appropriate sections along with instructions on the insertion of the restriction into the loan documents (§ 1965.65 (c)(1) and (f)(8) 1965.70 (a) and (d)(8) of Subpart B of Part 1965).

5. The format of § 1965.90 of Subpart B of Part 1965 will be reorganized to separate actions to be taken by the borrower and those to be taken by the District Office.

6. Methods for dealing with violations of restrictive use clauses will be outlined (§ 1965.90(d)(8) of Subpart B of Part 1965).

7. The time period necessary for FmHA to approve prepayments is being extended to give personnel the time necessary to determine the potential impact of prepayment on tenants and whether prepayment can be accepted, as well as to notify tenants of the pending prepayments, issue the letters of priority entitlement, and prepare the prepayment report (§ 1965.90(a)(2)(i) of Subpart B of Part 1965).

List of Subjects

7 CFR Part 1930

Accounting, Administrative practice and procedure, Grant programs—Housing and community development, Loan programs—Housing and community development, Low and moderate income housing—Rental, Reporting requirements.

7 CFR Part 1944

Administrative practice and procedure, Aged, Handicapped, Loan programs—Housing and community development, Low and moderate income housing—Rental, Mobile homes, Mortgages, Nonprofit organizations, Rent subsidies, Rural housing, Farm labor housing, Grant Programs—

Housing and community development, Migrant labor, Public housing.

7 CFR Part 1965

Administrative practice and procedure, Low and moderate income housing—Rental, Mortgages.

Accordingly, FmHA proposes to amend Subpart C of Part 1930, Subparts D and E of Part 1944 and Subpart B of Part 1965 of Chapter XVIII, Title 7, Code of Federal Regulations as follows:

PART 1930—GENERAL

1. The authority citation for Part 1930 continues to read as follows:

Authority: 42 U.S.C. 1480, 7 CFR. 2.23, 7 CFR 2.70.

Subpart C—Management and Supervision of Multiple Family Housing Borrowers and Grant Recipients

2. In Exhibit B to Subpart C, paragraph VI C. 3. a. (5) is revised; paragraph VIII A.3. through VIII A.5. are redesignated as paragraphs VIII A.5 through VIII A.7.; paragraphs VIII A.1. and VIII A.2. are revised; new paragraphs VIII A.3. and VIII A.4. are added; paragraph VIII C. 20. is redesignated VIII C.22. and new paragraphs 20. and 21. are added to read as follows:

Exhibit B—Multiple Housing Management Handbook

VI. ***
C. ***
3. ***
a. ***

(5) Displacees, such as victims of natural disasters, eminent domain and prepayment of loans, to whom priority consideration may be given.

VIII. ***
A. ***

1. All leases will be in writing and must cover a period of one year, except that leases for LH may be for shorter periods where occupancy is typically seasonal, and leases signed after notification of intent to prepay but prior to prepayment may be for a term which ends on the date of prepayment. For leases in effect at time of publication of this regulation, this provision need not be put into effect until the next regularly scheduled tenant recertification is performed.

2. In areas where there is a concentration of non-English speaking individuals, leases and the established rules and regulations for the project written in both plain English and the non-English concentration language must be available to the tenants. The tenant should have the opportunity to

examine and execute either form of lease.

3. Leases should contain an appropriate escalation clause permitting changes in basic and/or market rents prior to the expiration of the lease. Rent changes would normally be necessary due to changing utility and other operating costs. Any changes must be approved by FmHA according to Exhibit C of this subpart. Leases must specify that no increases in rent will take place due to prepayment of the FmHA loan during the term of the lease.

4. Leases should contain a provision allowing termination prior to the expiration date if mutually agreed to by tenant and landlord.

* * *

C. ***

20. That in the event of borrower prepayment of the FmHA loan, all leases will be handled in accordance with Paragraph VIII A of this Subpart, and all procedures specified in § 1965.90 of Subpart B of Part 1965 of this Chapter will be followed. No rents may be increased by reason of prepayment for the term of the lease. An escalation clause for rent changes approved by FmHA for budgetary reasons will continue to be applicable.

21. That the lease may be terminated prior to expiration of its term if mutually agreeable to both tenant and landlord.

3. In Exhibit E to Subpart C, paragraph XV B.3. is revised to read as follows:

Exhibit E—Rental Assistance Program

XV. ***
B. ***

3. Suspension and transfer after a liquidation or prepayment. a. When a project with RA is liquidated through sale outside of the program or the loan is paid in full, the RA will be suspended and, subsequently, transferred to a different FmHA financed project in accordance with this exhibit.

b. When a tenant receiving RA is displaced or will be displaced from an FmHA project due to prepayment, and moves directly to another FmHA project, the RA the tenant was receiving may be transferred to the FmHA project to which the tenant moves. This will only be done if the transferring tenant will be given priority for RA, including the RA being transferred, at the project to which the move is being made. The transferring tenant will be given such priority if the following conditions are met:

(1) The tenant is eligible for RA in the new location in accordance with paragraph II A 1 of this exhibit.

(2) The tenant meets occupancy standards for the unit to which the move is made, in accordance with paragraph II A 3 of this exhibit.

c. If the unit of RA cannot be immediately transferred upon prepayment in accordance with paragraph 3b of this section, the RA the tenant was receiving should be placed in suspense to be transferred when the tenant moves if the following conditions are met:

(1) There are at the time of prepayment no vacant FmHA units in the market area for which the tenant is eligible.

(2) The tenant has priority placement on the waiting list of one or more FmHA-financed projects.

d. If the tenant does not move directly to a project to which RA can be transferred, the RA will be transferred to any FmHA project at the State Director's discretion, and the tenant will lose priority for RA.

e. The amount of funds transferred to the receiving project will be determined by following the formula:

Remaining RA funds in prepaid projects	X	# of units being transferred to receiving project
# of units of RA authorized in prepaid project		

f. The receiving project borrower need not submit Form FmHA 1944-25, "Request for Rental Assistance," but procedures for transferring RA and modifying RA agreements outlined in paragraphs V C and XV A 2 of this exhibit will be followed.

PART 1944—HOUSING

4. The authority citation for Part 1944 continues to read as follows:

Authority: 42 U.S.C. 1480; 7 CFR 2.23; 7 CFR 2.70.

Subpart D—Farm Labor Housing Loan Policies, Procedures and Authorizations

5. In § 1944.164, paragraph (p) is revised to read as follows:

§ 1944.164 Limitations and conditions.

(p) Prepayment of LH loan. The acceptance of a farm labor housing loan will make the borrower subject to the

prepayment restrictions contained in § 1944.176(c)(2) of this subpart.

6. In § 1944.176, paragraph (c)(3) is revised to read as follows:

§ 1944.176 Loan and/or grant closing.

(c) * * *

(3) Any borrower whose loan was approved prior to December 21, 1979, and was closed on or after the date with the prospective restrictive language in the Mortgage, Loan Resolution or Agreement should be notified that they have the option of having these instruments modified if they desire to do so. Any cost associated with the modification must, however, be borne by the borrower. Any action in this area should be approved by the Office of the General Counsel.

§ 1944.200 [Removed and reserved]

7. Section 1944.200 is removed and reserved.

Subpart E—Rural Rental Housing Loan Policies, Procedures and Authorizations

8. In § 1944.237, paragraph (e) is added to read as follows:

§ 1944.237 Subsequent RRH loans.

(e) A subsequent loan will be subject to the prepayment restrictions cited in § 1944.236(b)(4) of this subpart and the cited language for the subsequent loan, only, must be appended to the mortgage referencing all notes.

PART 1965—REAL PROPERTY

9. The authority citation for Part 1965 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart B—Security Servicing for Multiple Housing Loans

10. In § 1965.65, paragraph (a)(1)(i) is revised; paragraph (a)(1)(iv) is removed; current paragraph (a)(1)(v) is redesignated as (a)(1)(iv); paragraphs (c)(1) through (c)(14) are redesignated as (c)(2) through (c)(15) and a new (c)(1) is added; paragraph (f)(6)(iv) is removed; paragraphs (f)(8) through (f)(13) are redesignated as (f)(9) through (f)(14) and a new paragraph (f)(8) is added to read as follows:

§ 1965.65 Transfer of real estate security and assumption of loans.

(a) * * *

(1) * * *

(i) Title to the security property is transferred, either when the project is

sold or through a change in the borrowing legal entity, such that the new entity is considered a distinct and separate legal entity from the original borrower, or:

(c) * * *

(1) All transfers to eligible borrowers will subject the borrower to the prepayment restrictions contained in § 1965.90 of this subpart.

(f) * * *

(8) All RRH, RCH and LH loans including those approved prior to December 21, 1979, which are transferred to eligible applicants will become subject to the prepayment requirement of section 502(c) of Title V, Housing Act of 1949, as amended. The restrictive language concerning prepayment set forth in § 1965.90(b)(2)(i) of this subpart must be appended, with the advice of OGC, to the assumption agreement and loan agreement/resolution. The prepayment restriction period will begin on the date the transfer and assumption is closed.

11. In § 1965.70, paragraph (a) is amended to add a sentence to the end of the paragraph, and paragraph (d)(8) is revised to read as follows:

§ 1965.70 Reamortization.

(a) * * * The reamortization of an account will make the borrower subject to the prepayment restrictions contained in § 1965.90 of this subpart.

(d) * * *

(8) The prepayment provisions of section 502(c) of Title V, Housing Act of 1949, as amended will apply. The appropriate restrictive language set forth in § 1965.90(b)(2)(i) of this subpart for RRH, RCH or LH loans will be appended, with the advice of OGC, to the loan agreement/resolution as a condition of FmHA approval of the action.

12. Section 1965.90 is revised to read as follows:

§ 1965.90 Payment in full.

(a) General requirements. Payment in full of an FmHA loan requires certain actions be taken by FmHA to evidence satisfaction of the account and to ease the transition of the tenants that may be affected by the conversion of a federally-financed project to a conventionally-financed one. The borrower's cooperation in these actions will assist in the orderly close-out of the account.

(1) *Final installments.* Borrowers should advise the District Office servicing the account of any final installment payment to facilitate the prompt preparation of any required releases and closeout actions.

(2) *Prepayment.* Borrowers seeking to prepay a multiple family housing loan must:

(i) Submit a written request to prepay at least 180 days in advance of the anticipated prepayment date.

(ii) Certify that they will continue to administer housing in accordance with Fair Housing policies.

(3) *Denial of prepayment request.* Any borrower denied a request to prepay will receive a letter stating the reasons for the denial and the right of the borrower to appeal the decision in accordance with Subpart B of Part 1900 of this chapter.

(b) *Special requirements—(1) Applicability of prepayment restrictive clause to loans approved prior to December 21, 1979.* Prepayment restrictive use clauses are not normally required to be inserted in a deed of release, satisfaction of mortgage, or other conveyance instrument for multiple family housing loans approved prior to December 21, 1979, unless such loans were later made subject to prepayment restrictions due to a transfer and assumption on same or new terms except to ineligible borrowers or reamortization of the loan.

(2) *Applicability of prepayment restrictive clause to loans approved on or after December 21, 1979, or subsequently made subject to prepayment restrictions.* For any multiple family housing loan approved on or after December 21, 1979, or which has been subsequently made subject to the prepayment restrictions of section 502 of Title V of the Housing Act of 1949, as amended, prepayments may be accepted only if the title to the real property is made subject to the applicable restrictive use clause set out at paragraph (b)(2)(i) or (b)(2)(ii) of this section or an exception in accordance with paragraph (b)(3) of this section can be granted. The restrictive period is: Fifteen years from the date on which the loan was closed or subsequently made subject to such prepayment period as a result of a servicing action as specified in this subpart, whichever is later; and a which has not received interest credit, rental assistance, or section 8 assistance; or twenty years from the date on which the loan was closed or subsequently made subject to such prepayment period as a result of a servicing action as specified in this subpart, whichever is later, in the case of any other loan.

(i) Project loans subject to this section as a result of a servicing action as set forth in paragraph (b)(1) of this section, with outstanding FmHA debt, will have the following prepayment restrictive use clause inserted in the deed, conveyance instrument, loan agreement/resolution, assumption agreement, or reamortization agreement, as appropriate.

"The borrower and any successors in interest agree to use the housing for the purpose of housing people eligible for occupancy as provided in section 514 or section 515 of Title V of the Housing Act of 1949 and FmHA regulations then extant during this — (15 years for unsubsidized and 20 years for subsidized loans) year period beginning — (the date the last loan on the project is closed or the project was made subject to the prepayment restrictions as a result of servicing actions authorized under this subpart or other subparts). No person occupying the housing shall be required to vacate prior to the close of such — (15 years for unsubsidized and 20 years for subsidized loans) year period because of early prepayment. The borrower will be released during such period from these obligations only when the Government determines that there is no longer a need for such housing or that such other financial assistance provided to the residents of such housing will no longer be provided. A tenant may seek enforcement of this provision as well as the Government."

(ii) Project loans subject to this section, which are being prepaid, for which any exception to the restrictive-use clause cannot be granted, will have the following restrictive use clause inserted in the deed, conveyance instrument, deed of release or satisfaction, as appropriate:

"The owner agrees that the housing located on this property will be used only as authorized under section 514 or 515 of Title V of the Housing Act of 1949, as amended, and FmHA regulations then extant until — (insert date, 15 years for unsubsidized or 20 years for subsidized loans from the date the last loan on the project was closed or the project was made subject to the prepayment restrictions as a result of servicing actions authorized under this subpart or other subparts). A tenant may seek enforcement of this provision as well as the United States. No person occupying the housing shall be required to vacate during such period because of early prepayment. The owner also agrees to post a notice at the project, in a place available for tenant inspection, stating that the project is to be used in accordance with the Housing Act for the

remainder of the restricted period. Exhibit A of this Subpart sets forth the format for this notice."

(3) *Exception to prepayment restrictive use clause.* An exception may be made to the prepayment restrictive use clause for projects when the State Director determines that:

(i) There is no longer a need for such housing and related facilities to be so utilized, or

(ii) Federal or other financial assistance provided to the residents of such housing will no longer be provided.

(4) the offer may not be accepted during the restrictive period (15 or 20 years) by the District Director when the State Director determines:

(i) That due to a change in the use of the housing and related facilities, or to an increase in rental or other charges likely to occur as a result of prepayment, the low- and moderate-income and elderly or handicapped tenants occupying the assisted housing at the time of the offer or request cannot reasonably be expected to remain in occupancy for such period. However, in spite of this determination, the offer or request to prepay may be processed only if affordable, decent, safe, sanitary and nonassisted alternative housing, or vacant assisted units for which there is not a waiting list, is available to the tenants who are likely to be displaced as a result of the change or increase, and

(ii) In the case of housing or related facilities containing more than 10 dwelling units, that the changes likely to occur as a result of the prepayment will have a substantial adverse effect on the supply of affordable, decent, safe, and sanitary housing available to low- and moderate-income and elderly or handicapped persons in the area in which the housing and related facilities are located.

(c) *Final payments and release of security.* The FmHA office charged with servicing the account must ensure payments in full and release of security are processed in the manner set out at Part 1866 of this chapter (FmHA Instruction 451.4) when real estate security is involved, and Subparts A and B of Part 1951, and Subpart A of Part 1962, as applicable, and appropriate program requirements and regulations. In all cases, references to County Supervisor shall be construed to mean District Director when applied to multiple family type borrowers. The District Director will notify the insurance company in writing that the government no longer has an interest in the fidelity bond and will release FmHA's interest in the insurance

policies according to the applicable provisions of Subpart A of Part 1806 of this chapter (FmHA Instruction 426.1). FmHA's interest in any other security will also be released in a manner prescribed by the State Director with the assistance of OGC, as necessary.

(d) *Special FmHA processing requirement.* Immediately upon receiving information regarding the prepayment of any RRH, RCH or LH loans, the District Director will:

(1) *Notification to tenants.* Notify each resident of the property by certified mail and prepare notices for the borrower to post in the project containing the following information (Exhibit B of this subpart is provided as a guide for this purpose):

(i) That the borrower plans to prepay the FmHA loan on a specified date and remove the housing from the FmHA program.

(ii) The level at which rents at the project are expected to be placed subsequent to prepayment.

(iii) That each tenant will be affected by this change at final lease expiration which will not occur prior to the prepayment.

(iv) That all displaced tenants and those experiencing rent overburden as defined in paragraph XIV A 4 of Exhibit B to Subpart C of Part 1930 of this chapter will be eligible for Letters of Entitlement that will place them at the top of all waiting lists for any FmHA project and units for which they qualify.

(v) Instructions on how to apply for a Letter of Entitlement; that they have up to 60 days prior to the termination of their final lease to apply for these letters; and that the letters will be valid for 60 days after receipt.

(vi) The names, location, number of apartments, and unit sizes of other FmHA projects in the market area and whether they serve senior citizens or families.

(vii) That those tenants on rental assistance (RA), who move directly to another FmHA project at which they are eligible for RA will receive priority for RA in the new project if the project borrower already has RA or is willing to accept and administer the RA.

(viii) That those tenants choosing to stay in their units after prepayment and pay the higher rents are entitled to do so, unless evicted for a cause unrelated to prepayment.

(ix) That in accordance with Title V of the Housing Act of 1949, as amended, which states that certain FmHA loans may be subject to restrictive-use covenants if the loan is prepaid, a tenant, as well as the government, may seek enforcement of the provisions.

(x) That all letters of priority will be issued in accordance with Title VI of the Civil Rights Act of 1964, and FmHA Instruction 1901-E.

(xi) Any other information pertinent to the particular case.

(2) *Prepayment report.* Send a report, completed in the format of Exhibit C of this subpart, on each prepayment case to the State Director for indefinite retention.

(3) *Acknowledgment letter.* Send an acknowledgement letter to the borrower upon receipt of any prepayment request. The letter must inform the borrower that prepayment commitments should not be finalized until the Agency issues a letter of consent. Receipt of a prepayment request less than 180 days in advance of the projected prepayment date may not be processed unless there is sufficient evidence that no tenant displacement will occur.

(4) *Letters of Priority Entitlement.* Notification on how and where to apply for a letter of entitlement will be posted in the project by the borrower at the time of notification of intent to prepay. The notices will remain posted until 60 days prior to the expiration of any leases still in effect. Upon receipt of a request for a letter of priority entitlement, the District Director will prepare a letter of priority entitlement which will include a statement that the affected tenant has 60 days to apply in writing with other FmHA RRH projects. The letter of priority entitlement will enable those tenants to be placed at the top of the waiting list for units in the projects for which they qualify. A list of FmHA RRH projects in the area will be included as part of the letter of priority entitlement. Eligible tenants in LH projects will also be advised of other available LH projects in the area.

(5) *Processing of a potential violation of the repayment restrictive use clause.* Should the District Office staff receive a written complaint or become otherwise aware of a violation of the prepayment restrictive use clause set out in paragraph (b)(2)(i) or (ii) of this section, by the owner of a previously FmHA-financed project, the following actions will be taken:

(i) The complainant will be informed that enforcement may be pursued through the courts.

(ii) The complaint will be subject to a preliminary evaluation which may warrant gathering added information. Should this preliminary evaluation indicate the complaint is not valid, the complainant will be so informed. Should the preliminary evaluation indicate the complaint is or may be valid, the complaint, facts gathered, evaluation report and staff recommendation will be

forwarded to the State Office for processing.

(iii) Should the State Office staff determine a violation of the provisions of paragraph (b)(2)(i) or (ii) of this section has likely occurred, the Administrator will be contacted. The OGC will be asked to provide advice in such cases. The complaint may then be referred to the Department of Justice or other appropriate Agency for enforcement. A copy of any complaint submitted to the Department of Justice or other appropriate Agency with a request to seek enforcement of the provisions of paragraph (b)(2)(i) or (ii) of this section should be forwarded to the Administrator.

(6) *Relationship with acceleration of accounts.* Accelerations should not be used as a means to circumvent the prepayment restrictive use clause provisions. Any prepayment of an FmHA loan subject to the provisions of paragraph (b)(2) of this section, prepaid in response to an acceleration of the account, will have the restrictive language contained in paragraph (b)(2)(ii) of this section inserted, with the advice of OGC, in the deed of release or satisfaction, as appropriate.

§ 1965.92 [Amended]

13. Section 1965.92 is amended in the third sentence by changing the reference "Exhibit B to this subpart (available in any FmHA office)" to "Exhibit D to this subpart (available in any FmHA office)."

14. Exhibit A to subpart B is redesignated as Exhibit B, new Exhibits A and C are added, and the newly redesignated Exhibit B is revised to read as follows:

[Exhibit A]

Exhibit for Borrower to Use as a Guide to Notify Tenants of Compliance with Title V of the Housing Act of 1949, As Amended

Notice to Tenants

This apartment complex was previously financed through the U.S. Department of Agriculture, Farmers Home Administration (FmHA). As a condition of paying off the FmHA indebtedness, the owners agreed to operate the complex in accordance with section 514 or section 515 of Title V of the Housing Act of 1949, as amended, and FmHA regulations until _____ (insert expiration date of 15 year period for unsubsidized or 20 year period for subsidized loans). This requires that apartments be rented to qualified low- and moderate-income tenants.

If you have any reason to believe that the requirements of the Housing Act of 1949 or the regulations of the FmHA are being violated in the operation of this complex, you are advised to contact the FmHA office listed below or any other FmHA office listed in the telephone directory under U.S. Government.

[Exhibit B]

Guide Letter to Notify Tenant of Pending Prepayment**Notice of Prepayment**

To: Tenants of (Name of Project)

On or about (date), the owners of (Name of Project) plan to pay off their FmHA loan and remove the housing from the FmHA program. At that time, rental rates may no longer be subsidized and it is anticipated that rental rates may change to approximately _____ for a _____ unit and _____ for a _____ unit. You would not be affected by these increases until such time as your final lease has expired, which will not be before the above date.

You may apply for a letter of priority placement on the waiting list of any FmHA financed project for which you qualify. You will have up to two months prior to the date your final lease expires to apply for this letter and it will be valid for 60 days after issue. If you are currently receiving rental assistance (RA) and you are eligible to receive RA at the project to which you are moving, you will receive priority for it at that project if the owner already has or is willing to accept the RA at the project. If you choose to stay in your apartment, and pay the higher rent, you may not be evicted without good cause.

Other FmHA projects in this area and the size of their units are:

In accordance with Title V of the Housing Act of 1949, as amended, tenants as well as the government may seek enforcement of the provisions under which an FmHA Multi-family housing loan may be prepaid.

All equal opportunity provisions apply to the issuance of the letters of priority.

If you have any questions or wish to apply for a letter of priority, please write or call:

District Director

[Exhibit C]

Report on Prepayment

1. Name of borrower.
2. Name of project.
3. Case number.
4. Date of initial loan approval.
5. Type of borrower entity and plan of operation.
6. The number of units in the project.
7. The number of eligible tenants presently occupying units.
8. The estimated replacement cost per unit.
9. The estimate of the number of households that will be displaced as a result of prepayment.
10. The estimated relocation cost of the households being displaced.
11. An indication of the displaced households' ability to pay relocation costs.
12. The income range of the tenants presently in the project.
13. The number of elderly tenants in the project.

14. The present rents and rents projected after prepayment.

15. The number and type of section 8 or RA units, and whether section 8 will continue after prepayment.

16. Any cause of displacement other than rent.

17. The availability of other vacant units in the area and their rental structure.

18. The District Office's recommendation on the final action.

19. Date of prepayment.

Dated: February 10, 1987.

Vance L. Clark,

Administrator, Farmers Home Administration.

[FR Doc. 87-5906 Filed 3-18-87; 8:45 am]

BILLING CODE 3410-07-M

FEDERAL HOME LOAN BANK BOARD**12 CFR Part 564**

[No.: 87-273]

Federal Savings and Loan Insurance Corporation, Settlement of Insurance

Dated: March 12, 1987.

AGENCY: Federal Home Loan Bank Board.

ACTION: Proposed rule; withdrawal.

SUMMARY: On April 17, 1985, the Federal Home Loan Bank Board ("Board"), as operating head of the Federal Savings and Loan Insurance Corporation ("FSLIC" or "Corporation") proposed comprehensive revisions to its regulations governing the FSLIC insurance coverage of deposit accounts ("Insurance Regulations"). A supplement to that notice was adopted on January 23, 1987. The Board has decided to study further the problems which the proposals were designed to address. Accordingly, the Board is today withdrawing the proposed regulation.

DATE: This withdrawal is effective March 19, 1987.

FOR FURTHER INFORMATION CONTACT:

Jerome Edelstein, Assistant Director, Regulations and Legislation Division, Office of the General Counsel, (202) 377-7057, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: On April 17, 1985, the Board proposed comprehensive revisions to its regulations governing settlement of insurance on deposit accounts in institutions the deposits of which are insured by the FSLIC. See Board Res. No. 85-286a, 50 FR 19185 (May 7, 1985). In a final rule adopted on April 4, 1986, the Board finalized one portion of the regulation relating to disclosure of trust accounts. See Board Res. No. 86-352, 51 FR 12122 (April 9, 1986). At that time, the Board stated that it would postpone finalization of other portions of the proposal pending further consideration. On January 23, 1987, the Board adopted a supplemental notice of proposed rulemaking relating to the effective date of any changes in the regulations as they pertain to certificates of deposit securing certain tax-exempt bonds. See Board Res. No. 87-100, 52 FR 3126 (February 2, 1987).

Experience with payment of insurance on accounts in defaulted institutions since the original April, 1985, proposal has brought to the attention of the Board issues not fully addressed by the proposed regulations. The Board

Office of International Cooperation and Development**7 CFR Part 2201****Indirect Costs Rates for Cooperative International Agricultural Development Programs; Withdrawal of Proposed Rule**

AGENCY: Office of International Cooperation and Development (OICD), USDA.

ACTION: Withdrawal of proposed rule.

SUMMARY: On Thursday, March 5, 1987 (52 FR 6803), the Office of International Cooperation and Development published a proposed rule to establish indirect cost rates for cooperative international agricultural development programs (7 CFR Part 2201). This proposed rule was inadvertently processed and signed without the benefit of Office of Management and Budget review required by Executive Order 12291. Accordingly, this proposed rule is being withdrawn. OICD intends to republish this rule after it has been properly processed.

DATE: This withdrawal is effective March 16, 1987.

FOR FURTHER INFORMATION CONTACT:

Dr. Tommey Cooper, Administration, Office of International Cooperation and Development, U.S. Department of Agriculture, Washington, DC 20250-4300, Telephone (202)653-8818.

Issued at Washington, DC.

Dated: March 16, 1987.

Tommey Cooper,

Acting Assistant Administrator for Administration.

[FR Doc. 87-5942 Filed 3-18-87; 8:45 am]

BILLING CODE 3410-DP-M

believes that the most appropriate way to address such issues is to develop revised proposed changes to the Insurance Regulations and seek comments on them.

Development of such revised changes also would give the Board an opportunity to work with the Federal Deposit Insurance Corporation in an effort to promulgate Insurance Regulations, which are uniform to the extent possible. Consequently, the Board hereby withdraws the proposed revisions to its Insurance Regulations contained in Resolution Nos. 85-286a and 87-100. Those portions of the proposed regulations finalized in Board Resolution No. 86-352 remain effective.

The Board emphasizes withdrawal of this proposal in no way indicates a modification of its longstanding position that:

No opinions, representations or other statements concerning the insurance coverage afforded in this Part or in Title IV of the National Housing Act, whether made by an insured institution or any other person, whether or not such person is employed by the Board or the Corporation, shall be considered to have any binding effect upon the Corporation or the Board. All opinions, statements, and other representations made by employees of the Board or the Corporation or any publication, other than pertinent resolutions of the Board, this Part, and the Appendix to Part 564, are advisory only.

This notice, which was included in the proposed regulations, 50 FR 19185, 19194 (1985), reaffirmed longstanding Board policy, which remains in effect. See 50 FR 19185, 1988; 32 FR 18122 (1967).

By the Federal Home Loan Bank Board.
Nadine Y. Washington,
Acting Secretary.

[FR Doc. 87-5964 Filed 3-18-87; 8:45 am]
BILLING CODE 6720-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 86-NM-219-AD]

Airworthiness Directives: McDonnell Douglas Model DC-8-62, -62F, -63, and -63F Series Airplanes, Modified in Accordance With Aeronautic Development Corporation Supplemental Type Certificate (STC) SA2494NM

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes a new airworthiness directive (AD), applicable to certain McDonnell Douglas Model DC-8-62, -62F, -63, and -63F series airplanes, which would require repetitive inspection and modification, as necessary, of the engine inlet nose dome extension aft attachment ring flanges. This proposal is prompted by reports of fatigue cracking of the nose dome extension aft attachment ring flanges. This condition, if not corrected, could lead to the loss of the engine inlet nose dome assembly, which can cause engine stalls and lead to subsequent engine in-flight shut down (IFSD) or other severe degradation of engine performance during critical flight regimes. The potential exists for multiple IFSD's.

DATE: Comments must be received no later than May 11, 1987.

ADDRESSES: Send comments on the proposal in duplicate to Federal Aviation Administration, Northwest Mountain Region, Office of the Regional Counsel (Attn: ANM-103), Attention: Airworthiness Rules Docket No. 86-NM-219-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. The applicable service information may be obtained from Rohr Industries, Inc., Post Office Box 878, Chula Vista, California 92012-0878, Attention: Robert Dickson. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or 4344 Donald Douglas Drive, Long Beach, California.

FOR FURTHER INFORMATION CONTACT:
Mr. David Y.J. Hsu, Aerospace Engineer, Airframe Branch, ANM-122L, FAA, Northwest Mountain Region, Los Angeles Aircraft Certification Office, 4344 Donald Douglas Drive, Long Beach, California 90808; telephone (213) 514-6319.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposal contained in this Notice may be changed in light of the comments received. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for

examination by interested persons. A report summarizing each FAA/public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the FAA, Northwest Mountain Region, Office of the Regional Counsel (Attn: ANM-103), Attention: Airworthiness Rules Docket No. 86-NM-219-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

Discussion

The FAA has received reports that operators of DC-8-62 and -63 series airplanes modified by Aeronautic Development Corporation STC SA2494NM have found thirty-two engine inlet extended nose dome assemblies with cracked or severed aft attachment ring flanges (lugs). Altogether there are ten flanges (lugs), five of which are used with mechanical fasteners to attach the assembly to the engine forward fan case. One operator has reported two incidents where, in one case, one of the five flanges was severed while the remaining four were cracked, and in the other case, four of the five flanges were cracked. Twelve airplanes were identified as having two, three, and four engines with cracked attachment flanges on their extended nose dome assemblies. Airplanes with cracked flanges had accumulated from 480 to 3280 flight hours since installation. Preliminary investigation of the cracked assemblies by the manufacturer indicates that the cracking is attributable to metal fatigue.

This condition, if not corrected, could lead to the loss of the engine inlet nose dome assembly, which can cause engine stalls and lead to subsequent engine in-flight shut downs (IFSD) or other severe degradation of engine performance during critical flight regimes. The potential exists for multiple IFSD's.

The FAA has reviewed and approved Rohr Industries, Inc., Alert Service Bulletin QDC8-A71-10, dated October 21, 1986, which provides instructions for repetitive inspection of the aft attachment ring flanges (lugs) of the engine inlet extended nose dome and rework if cracks are found.

Further investigation by the manufacturer has resulted in Revision 1 to Rohr Industries, Inc., Alert Service Bulletin QDC8-A71-10, dated November 20, 1986. This revision clarifies and expands the information presented in

the original issue of the bulletin and is, likewise, FAA approved.

Since this condition is likely to exist or develop on other airplanes of this same type design, an AD is proposed which would require repetitive inspection for fatigue cracks at the aft attachment flanges of the engine inlet nose dome extension and modification, as necessary, in accordance with the service bulletin previously mentioned.

It is estimated that 24 airplanes of U.S. registry and 5 U.S. operators would be affected by this AD, that it would take approximately 8 manhours per airplane to accomplish the required actions, and that the average labor cost would be \$40 per manhour. Based on these figures, the total cost impact for all U.S. operators to accomplish the initial inspection is estimated to be \$7,680. The recurring inspection costs to the affected operators are estimated to be 56 manhours per airplane per year, at an average labor cost of \$40 per manhour. Based on these figures, the annual recurring cost of this AD for U.S. operators is estimated to be approximately \$53,760.

For these reasons, the FAA has determined that this document (1) involves a proposed regulation which is not major under Executive Order 12291 and (2) is not a significant rule pursuant to the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities because few, if any, Model DC-8 airplanes are operated by small entities. A copy of a draft regulatory evaluation prepared for this action is contained in the regulatory docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

The Proposed Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By adding the following new airworthiness directive:

McDonnell Douglas: Applies to McDonnell Douglas Model DC-8-62, -62F, -63, and -63F series airplanes, modified in accordance with Aeronautic Development Corporation Supplemental Type Certificate (STC) SA2494NM, certificated in any category. Compliance required as indicated, unless previously accomplished.

To prevent the loss of engine inlet extended nose dome assembly due to metal fatigue failure of the aft attachment ring flanges and damage to the engine, within 250 flight-hours after the effective date of this AD, unless already accomplished within last 250 flight-hours, accomplish the following:

A. Visually inspect nose dome extension aft attachment ring flanges, Rohr Industries, Inc., Part Number 236-0002, in accordance with paragraph 2.A. of Rohr Industries, Inc., Alert Service Bulletin QDC8-A71-10, dated October 21, 1986, or later revisions approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: Removal of the nose dome extension requires disconnecting the PT₂ probe sense line extension. Care must be taken to ensure proper connection when re-installing to prevent erroneous EPR indication.

B. If no cracks are found, repeat the visual inspection of the flanges in accordance with paragraph A. of this AD, at intervals not to exceed 500 flight-hours.

C. If cracks are found on flanges with attachments, accomplish the following before further flight:

1. For extended nose dome with five alternate blank flanges:

a. Relocate the five attachments in accordance with paragraph 2.A.(3) through 2.A.(13) of the Rohr Industries, Inc., Alert Service Bulletin QDC8-A71-10, dated October 21, 1986, or later revisions approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

b. Repeat visual inspection of the flanges at the relocated attachments in accordance with paragraph A. of this AD, at intervals not to exceed 500 flight-hours.

2. For extended nose dome without the five alternate blank flanges:

a. Remove and replace the aft attachment ring of the extended nose dome in accordance with FAA approved data.

b. Repeat visual inspection of the flanges of the newly installed attach rings in accordance with paragraph A. of this AD, at intervals not to exceed 500 flight-hours.

D. Alternate means of compliance which provide an acceptable level of safety may be used when approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

E. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to Rohr Industries, Inc., Post Office Box 878, Chula Vista, California

92012-0878; Attention: Robert Dickenson. These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or at 4344 Donald Douglas Drive, Long Beach, California.

Issued in Seattle, Washington, on March 12, 1987.

Frederick M. Isaac,

Acting Director, Northwest Mountain Region.

[FR Doc. 87-5877 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 86-NM-213-AD]

Airworthiness Directives: Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Withdrawal of notice of Proposed rulemaking.

SUMMARY: This action withdraws a Notice of Proposed Rulemaking (NPRM) which proposed to amend an existing airworthiness directive (AD), applicable to certain Boeing Model 747 airplanes, that currently requires inspection for loose or failed bolts used for the forward attachment of the Numbers 1, 2, 3, 6, 7, and 8 trailing edge flap tracks to the wing lower surfaces. The proposal would have revised the applicability statement to reference Revision 1 of the Boeing Service Bulletin and to include 13 additional affected airplanes. Since issuance of the NPRM, the FAA has determined that the 13 additional airplanes were modified prior to delivery so as to eliminate the unsafe condition. Therefore, the FAA has determined that the applicability of the existing Ad is correct. Accordingly, the NPRM is withdrawn.

FOR FURTHER INFORMATION CONTACT:

Mr. Owen Schrader, Airframe Branch, ANM-120S; telephone (206) 431-1923. Mailing address: FAA Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation regulations to amend an existing airworthiness directive, applicable to certain Boeing Model 747 airplanes, was published in the *Federal Register* on November 26, 1986 (51 FR 42851). The proposal would have amended Ad 86-18-06, Amendment 39-5386 (51 FR 28061; August 5, 1986), to require inspection for loose or failed bolts, used for the forward attachment

of the Numbers 1, 2, 3, 6, 7, and 8 trailing edge flap tracks to the wing lower surfaces, on 13 additional affected airplanes omitted from the applicability statement in the AD. Since issuance of the NPRM, the manufacturer has presented FAA with inspection records of the 13 subject airplanes, which indicate that the bolts on these airplanes had been modified (retorqued) prior to delivery so as to eliminate the unsafe condition. Accordingly, the FAA has determined that the proposed amendment is not necessary, and the NPRM is hereby withdrawn.

Withdrawal of this Notice of Proposed Rulemaking constitutes only such action, and does not preclude the agency from issuing another Notice in the future, or commit the agency to any course of action in the future.

Since this action only withdraws a Notice of Proposed Rulemaking (NPRM), it is neither a proposed nor final rule, and therefore, is not covered under Executive Order 12291, the Regulatory Flexibility Act, or DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979).

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

The Withdrawal

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration withdraws a proposal to amend § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By withdrawing the Notice of Proposed Rulemaking, Docket 86-NM-213-AD, published in the **Federal Register** on November 26, 1986 (51 FR 42851), FR Doc. 86-26581.

Issued in Seattle, Washington, on March 12, 1987.

Federick M. Isaac,
Acting Director, Northwest Mountain Region.
[FR Doc. 87-5876 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 87-ASW-3]

Airworthiness Directives; Sikorsky Model S-61A, S-61L, S-61N, S-61NM, S-61R, and S-61V Series Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to adopt an airworthiness directive (AD) that would reduce the retirement life of the main gearbox servo support bracket and servo support bracket assembly of the Sikorsky Model S-61L, S-61N, S-61NM, and S-61R helicopters certificated in all categories and S-61A and S-61V helicopters certificated in the restricted category. The proposed AD is needed to prevent failure of the servo support bracket assembly, which could result in loss of altitude control of the helicopter.

DATE: Comments must be received on or before May 1, 1987.

ADDRESSES: Comments on the proposal may be mailed in duplicate to: Office of the Regional Counsel, FAA, Southwest Region, P.O. Box 1689, Fort Worth, Texas 76101, or delivered in duplicate to: Office of the Regional Counsel, FAA, Southwest Region, Room 158, Building 3B, 4400 Blue Mound Road, Fort Worth, Texas 76106. Comments delivered must be marked: Docket No. 87-ASW-3. Comments may be inspected at Room 158, Building 3B, Office of the Regional Counsel, Southwest Region, between the hours of 8 a.m. and 4 p.m. weekdays, except Federal holidays.

Copies of the applicable sections of the maintenance manual for installation and removal of the bracket assembly may be obtained from: Sikorsky Aircraft, 6900 Main Street, Stratford, Connecticut 06601-1381.

FOR FURTHER INFORMATION CONTACT: Terry Fahr, FAA, ANE-153, 12 New England Executive Park, Burlington, Massachusetts 01803, telephone (617) 273-7102.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Director before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket, Office of the Regional Counsel, 4400 Blue Mound Road, Fort Worth, Texas, for

examination by interested persons. A report summarizing each FAA-public contact, concerned with the substance of the proposed AD, will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 87-ASW-3." The postcard will be date/time stamped and returned to the commenter.

The FAA has determined that certain Sikorsky Model S-61 main gearbox servo support brackets (P/N S6135-20248) have experienced a reduction in service life as a result of service history wear caused by certain main gearbox servo trunnions (P/N S6135-20232) having excess material on their corners. Also, further analysis by the manufacturer has confirmed a need for reduction in the retirement life of the primary servo bracket and bracket assembly due to the interference wear. Since this condition is likely to exist or develop on other helicopters of the same type design, the proposed AD would reduce the retirement life of the main gearbox servo bracket and bracket assembly.

The FAA has determined that this proposed regulation only involves 15 aircraft with negligible cost to each aircraft. Therefore, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) if promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained by contacting the persons identified under the caption "**FOR FURTHER INFORMATION CONTACT.**"

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me, the FAA proposes to amend § 39.13 of Part 39 of the FAR as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421, and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.85.

§ 39.13 [Amended]

2. By adding the following new AD:

Sikorsky Aircraft: Applies to Model S-61L, S-61N, S-61NM and S-61R helicopters certificated in all categories and S-61A and S-61V helicopters certificated in restricted category equipped with main gearbox servo cylinder support brackets (P/N S6135-20248-0 and -2) or bracket assemblies (P/N S6135-20249-0 and -1).

Compliance is required as indicated unless already accomplished.

To preclude possible fatigue failure of the main gearbox servo support bracket (P/N S6135-20248-0 and -2) or bracket assembly (P/N S6135-20249-0 and -1) accomplish the following:

(a) Replace the P/N S6135-20248-0 and -2 servo support brackets or the P/N S6135-20249-0 and -1 support bracket assemblies with serviceable parts in accordance with the following schedule:

(1) For Model S-61A, S-61L, S-61N, S-61NM, and S-61V helicopters, replace the servo support bracket or assembly within the next 25 hours' time in service after the effective date of this AD or before the accumulation of 23,200 hours' time in service on the bracket or assembly, whichever occurs later. Thereafter, replace the bracket or assembly in intervals not to exceed 23,200 hours' time in service.

(2) For the Model S-61R helicopter, replace the servo support bracket or assembly within the next 25 hours' time in service after the effective date of this AD or before the accumulation of 6,200 hours' time in service on the bracket or assembly, whichever occurs later. Thereafter, replace the bracket or assembly in intervals not to exceed 6,200 hours' time in service.

(b) Operators who have not kept records of hours' time in service on individual component parts that were installed at time of issuance of the initial rotocraft airworthiness certificate shall substitute rotocraft hours' time in service.

(c) For purposes of complying with this AD, the hours' time in service for individual components that were not installed at the time of issuance of the initial rotocraft airworthiness certificate must be determined from operator's rotocraft records.

(d) Unless request, an alternate means of compliance which provides a level of safety equivalent to the requirements of this AD may be used when approved by the Manager, Boston Aircraft Certification Office, 12 New England Executive Park, Burlington Massachusetts 01803, telephone (617) 273-7118.

(e) Upon submission of substantiating data by an owner or operator through an FAA maintenance inspector, the Manager, Boston Aircraft Certification Office, 12 New England

Executive Park, Burlington, Massachusetts 01803, telephone (617) 273-7118, may adjust the compliance time specified in this AD.

Issued in Fort Worth, Texas, on March 3, 1987.

Don P. Watson,

Acting Director, Southwest Region.

[FR Doc. 87-5873 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 84-ASW-41]

Airworthiness Directives; Costruzioni Aeronautiche Giovanni Agusta S.p.A. Model A109A and A109A II Series Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to amend an existing airworthiness directive (AD) which requires an initial inspection and repetitive checks for cracks in the tail rotor blade grip on Agusta Model A109A and A109A II helicopters. This proposed amendment is needed to clarify that the inspections are required only for tail rotor blades, Part Numbers (P/N 109-0132-02-11 and -15).

DATE: Comments must be received on or before May 1, 1987.

Compliance: As indicated in the body of the AD.

ADDRESSES: Comments on the proposal may be mailed in duplicate to: Office of the Regional Counsel, FAA, Southwest Region, P.O. Box 1689, Fort Worth, Texas 76101, or delivered in duplicate to: Office of the Regional Counsel, FAA, Southwest Region, Room 158, Building 3B, 4400 Blue Mound Road, Fort Worth, Texas 76106. Comments delivered must be marked: Docket No. 84-ASW-41. Comments may be inspected in Room 158, Building 3B, Office of the Regional Counsel, Southwest Region, between 8 a.m. and 4 p.m., weekdays, except Federal holidays.

The applicable service information may be obtained from Agusta Aviation Corporation, N.E. Service Center, Norcom and Red Lion Roads, Philadelphia, Pennsylvania 19154.

A copy of the service bulletin is contained in the Rules Docket, Office of the Regional Counsel, FAA, Southwest Region, 4400 Blue Mound Road, Fort Worth, Texas 76106.

FOR FURTHER INFORMATION CONTACT: John Varoli, Manager, Brussels Aircraft

Certification Office, Federal Aviation Administration, c/o American Embassy, APO New York 09667-1011, or Robert Weaver, Rotocraft Standards Staff, Federal Aviation Administration, Southwest Region, 4400 Blue Mound Road, Fort Worth, Texas 76106, telephone (817) 624-5122.

SUPPLEMENTARY INFORMATION:

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Director before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket, Office of the Regional Counsel, 4400 Blue Mound Road, Fort Worth, Texas, for examination by interested persons. A report summarizing each FAA-public contact, concerned with the substance of the proposed AD, will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments of Docket No. 84-ASW-41." The postcard will be date/time stamped and returned to the commenter.

After issuing Amendment 39-5043 (50 FR 18240), the FAA has determined that the manufacturer has designed new, improved parts which provide an equivalent level of safety without daily checks or special 25-hour inspections. Therefore, the FAA is proposing to amend Amendment 39-5043 by making it applicable only to Agusta Model A109A and A109A II helicopters equipped with tail rotor blades with P/N 109-0132-02-11 or -15. The AD will not be applicable to the new, improved blades with P/N 109-0132-02-121.

The FAA has determined that this regulation only involves a maximum of 50 aircraft with a cost of only \$1,500 per fleet inspection (\$30 per aircraft). Therefore, I certify that this action (1) is

not a "major rule" under Executive Order 12291, (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) if promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained by contacting the person identified under the caption "**FOR FURTHER INFORMATION CONTACT.**"

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the FAR as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421, and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.85.

§ 39.13 [Amended]

2. By amending Amendment 39-5043 (50 FR 18240), AD 84-13-06, by revising the applicability paragraph to limit the AD to Model A109A and A109A II series helicopters equipped with P/N 109-0132-02-11 or -15 tail rotor blades and by revising paragraphs (a) and (b) as follows:

Costruzioni Aeronautiche Giovanni Agusta S.p.A.: Applies to Model A109A and A109A II series helicopters equipped with P/N 109-0132-02-11 or -15 tail rotor blades certified in all categories.

Compliance is required as indicated unless already accomplished.

(a) Within the next 10 hours' time in service, inspect the tail rotor blade grip in accordance with Part I of Agusta Service Bulletin (SB) 109-51, Revision A, or an FAA-approved equivalent, and at each additional 25 hours' time in service, accomplish the inspection of Part II of Agusta SB 109-51, Revision A, or an FAA-approved equivalent.

(b) Prior to the first flight of each day, accomplish the airworthiness check of Part II of Agusta SB 109-51, Revision A, or an FAA-approved equivalent. The check required by this AD may be performed by the pilot.

Issued in Fort Worth, Texas, on March 3, 1987.

Don P. Watson,

Acting Director, Southwest Region.

[FR Doc. 87-5874 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM87-4-000]

Electric Utilities; Rate Changes Relating to Federal Corporate Income Tax Rate For Public Utilities

Issued: March 12, 1987.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of proposed rulemaking.

SUMMARY: Congress recently enacted the Tax Reform Act of 1986 that, among other changes, reduced the Federal corporate income tax rate by twelve percentage points (from 46 percent to 34 percent), effective July 1, 1987. The Federal Energy Regulatory Commission (Commission) is proposing procedures for ensuring that the rates of public utilities reflect the change in the Federal corporate income tax rate.

DATE: Written comments must be filed with the Commission by April 20, 1987.

ADDRESS: Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT: Julia Lake White, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 (202) 357-8530.

SUPPLEMENTARY INFORMATION:

I. Introduction

Congress recently enacted the Tax Reform Act of 1986 that, among other changes, reduced the Federal corporate income tax rate by twelve percentage points (from 46 percent to 34 percent), effective July 1, 1987. The Federal Energy Regulatory Commission (Commission) is proposing procedures for ensuring that the rates of public utilities reflect the change in the Federal corporate income tax rate.¹

¹ The term "public utility" as used throughout this Notice is as defined in section 201(e) of the Federal Power Act, 16 U.S.C. 824 (1982). It thus refers solely to electric utilities, as opposed to natural gas and oil pipeline utilities. Although the Tax Reform Act of 1986 impacts in a number of ways on the rates of all companies subject to the Commission's ratemaking jurisdiction, the Commission is particularly concerned that all public utilities reflect the decrease in the Federal corporate income tax rate in their jurisdictional rates. Natural gas pipeline companies' rates will automatically be adjusted since tax trackers have been included in the majority of the natural gas pipeline companies' rate settlements. Changes in oil pipeline rates will be done on a case-by-case basis.

The Commission first proposes to adopt an abbreviated filing procedure which will enable a public utility to voluntarily reduce its rates under section 205 of the Federal Power Act (FPA) to reflect the reduction in the Federal corporate income tax rate. The Commission is proposing this procedure as a means of encouraging public utilities to expeditiously file such rate reductions so as to allow them to take effect as of July 1, 1987.

The primary option being proposed by the Commission under this voluntary procedure would permit a public utility to reflect the reduction in the Federal corporate income tax rate through a formulary reduction in its existing rates. This formula would rely upon data submitted by a public utility to support its present rate levels. As an alternative, the Commission is requesting comments on the use of a generically-determined, fixed percentage reduction to the demand charge component of a public utility's existing rates. Comments are also invited on whether both of these proposals should be adopted and codified as filing options available to a public utility to facilitate the submission of voluntary rate reductions for rates based on a test year cost of service study. It is noted that cost of service formulary rates do not fall within the scope of this proposed rulemaking.

In the event that a public utility does not avail itself of the opportunity to voluntarily reduce its rates, the Commission may institute "show cause" proceedings on the basis that rates reflecting a 46 percent tax rate may constitute unjust and unreasonable rates under section 206 of the Federal Power Act. Utilities exempted under this procedure would be those public utilities that have rate filings pending before the Commission in which the tax component can be changed and in which the effective date of the rates at issue therein is no later than July 1, 1987; those that tender rate change applications to allow an effective date no later than July 1, 1987; or those whose rates already reflect the change in the Federal corporate income tax rate.

II. Background

On October 22, 1986, the President signed the Tax Reform Act of 1986.² The Tax Reform Act of 1986 provides for a number of changes in the Federal tax system, three of which will most affect jurisdictional companies. First, the tax law retains provisions for accelerated depreciation, but at reduced levels.

² Pub. L. No. 99-514, 100 Stat. 2085-2963 (1986) [to be codified at 26 U.S.C. 1-7872].

Second, investment tax credits, except for transitional property, are eliminated for property placed in service after January 1, 1986. Finally, the Federal corporate income tax rate is reduced to 34 percent effective July 1, 1987.

The last time the Commission had an opportunity to address a Federal corporate income tax rate change was in 1978 when Congress reduced the Federal corporate income tax rate from 48 percent to 46 percent. At that time, the Commission did not issue a statement of policy or a final rule, but rather, considered this tax rate change issues on a case-by-case basis in rate proceedings.³ Since the change in the Federal corporate income tax rate under the Tax Reform Act of 1986 represents a dramatic decrease (from 46 percent to 34 percent), the Commission is proposing a rule to encourage the timely filing of lower rates by public utilities to reflect the new Federal corporate income tax rate.

III. Discussion

A. An Overview

To the extent the filed rates of natural gas pipelines, oil pipelines, and public utilities provide for the overrecovery of Federal income tax expense, the Commission is concerned that these rates may constitute unjust and unreasonable rates under section 206 of the Federal Power Act,⁴ section 5 of the Natural Gas Act,⁵ and section 6 of the Interstate Commerce Act.⁶

1. Tax Depreciation

The Tax Reform Act of 1986 modifies the existing Accelerated Cost Recovery System (ACRS) which provides for tax depreciation of qualified property. The new system, Modified Accelerated Cost Recovery System (MACRS), will apply, except for transitional property, only to property placed in service after December 31, 1986.

Despite changes in the rules governing tax depreciation, however, a jurisdictional company's revenue requirements should not be significantly changed initially by the reduced amount of tax depreciation available under the new tax law. Under the Commission's tax normalization policy,⁷ the allocation

of tax expenses over time relating to depreciation is based upon the level of book depreciation taken, not tax depreciation. The amount of book depreciation to be taken each year is unchanged by the Tax Reform Act of 1986. For this reason, the immediate effect upon a jurisdictional company's revenue requirement will be, for the most part, limited to the reduced amount of accumulated deferred income taxes that will be recorded in its financial statement and used as a rate base deduction.

2. Investment Tax Credits

Under current Commission regulatory policy,⁸ the benefits of investment tax credits are shared between ratepayers and stockholders of the regulated company. They are shared through a Federal tax law requirement that the investment tax credits be deferred and amortized over the service life of the property to which they relate.⁹ Ratepayers benefit by either receiving the time value of the investment tax credit (through a reduction to ratebase by the unamortized investment tax credit amount) or receiving the corpus of the credit (through a direct amortization to the test period income tax calculation). Under either option elected by the jurisdictional company, the benefit of the investment tax credit is passed through to ratepayers over the life of the asset that generated the credit. For that reason, the Commission anticipates that the *immediate* effect upon revenue requirements, if any, resulting from the loss of the investment tax credits will be slight. Previously-generated investment tax credits will continue to be reflected in rates until fully amortized.

3. Corporate Income Tax Rate Reduction

Overshadowing the very minimal cost of service impact of the above two items will be the substantial reduction in revenue requirements that is expected to result from the new Federal corporate income tax rate. Rate reductions due to the lower Federal corporate income tax rate may be necessary since the reduction in the Federal corporate income tax rate from 46 percent to 34 percent indicates that the tax allowance component of rates under the Commission's ratemaking model should

be reduced by approximately 40 percent.¹⁰ For example, staff performed an analysis of a selected sample of recent cost of service studies filed by public utilities providing firm service, which demonstrated that the change in the Federal corporate income tax rate could result in substantial overrecoveries by the public utilities. Staff's analysis, which focused solely upon the change in the Federal corporate income tax rate, indicates that these public utilities would collect excess revenues ranging from five to eight percent of the nonvariable cost portion of total revenue requirements.

4. Impact of Change in Federal Corporate Income Tax Rate on Deferred Income Taxes

The Commission, through its adoption of Order No. 144 and Order No. 144-A¹¹ has adopted a ratemaking and accounting policy of full interperiod tax normalization. Order Nos. 144 and 144-A also require jurisdictional companies to file a rate plan for amortizing any excess or deficiency in the deferred taxes in the company's accounts.¹² For example, the "South Georgia Method"¹³ used by many of the jurisdictional companies to systematically bring deferred tax balances into accord with deferred tax requirements in consistent with Order No. 144. Since public utilities must file a rate plan for amortizing any excess or deficiency in deferred taxes,

¹⁰ The percentage change in the income tax component of a jurisdictional company's revenue requirement due to a reduction in the Federal corporate income tax rate can be measured by the incremental change in the "income tax factor." This factor, expressed as the Federal tax rate divided by one minus the Federal tax rate, is 0.85185 at the 46 percent rate and 0.51515 at the 34 percent rate. Thus, the 12 percentage point reduction in the Federal tax rate translates to nearly a 40 percent reduction in a jurisdictional company's income tax allowance.

¹¹ "Regulations Implementing Tax Normalization for Certain Items Reflecting Timing Differences in the Recognition of Expenses or Revenues for Ratemaking and Income Tax Purposes," Order No. 144, 46 FR 26613 (May 14, 1981), FERC Stats. & Regs. [Regulations Preambles 1977-1981] ¶ 30.254 (May 6, 1981); "Order Denying Rehearing, Lifting Stay and Clarifying Order," Order No. 144-A, 47 FR 8329 (Feb. 26, 1982) and 47 FR 8991 (Mar. 3, 1982), FERC Stats. & Regs. [Regulations Preambles 1982-1985] ¶ 30.340 (Feb. 22, 1982).

¹² Order No. 144, in effect, requires that jurisdictional companies measure their total deferred tax requirements by multiplying their cumulative timing differences by the current statutory tax rate, compare this computed requirement with accumulated deferred taxes recorded on their books, and file a rate plan for amortization of any excess or deficiency. The reasons for the excess or deficiency are generally attributable to changes in tax rates and prior "flow-through" rate and accounting policies.

¹³ See Order No. 144, FERC Stats. & Regs. [Regulations Preambles 1977-1981] ¶ 30.254 at 31,559-31,560 (May 6, 1981); Memphis Light, Gas and Water Div. v. FERC, 707 F.2d 565 (D.C. Cir. 1983).

³ See, e.g., Virginia Electric and Power Company, 10 FERC ¶ 61.063 (1980) and Public Service Company of New Mexico, 10 FERC ¶ 61.053 (1980).

⁴ 16 U.S.C. 824(e) (1982).

⁵ 16 U.S.C. 717(d) (1982).

⁶ 49 U.S.C. 15 (1976).

⁷ See 18 CFR 35.25 and 154.63(a) (1986).

"Regulations Implementing Tax Normalization for Certain Items Reflecting Timing Differences in the Recognition of Expenses or Revenues for Ratemaking and Income Tax Purposes", Order No. 144, 46 FR 26613 (May 14, 1981), FERC Stats. & Regs.

[Regulations Preambles 1977-1981] ¶ 30.254 (May 6, 1981).

⁸ See, e.g., "Ratemaking Treatment of Investment Tax Credits for Natural Gas Pipeline Companies," Order No. 440, 50 FR 49679 (Dec. 4, 1985), FERC Stats. & Regs. [Regulations Preambles 1982-1985] ¶ 30.674 (Nov. 27, 1985). See also Southwestern Public Service Company, Opinion No. 162, 22 FERC ¶ 61,341 (1983).

⁹ I.R.C. section 46(f) (1982).

no new procedures to reduce the deferred tax account are proposed here.

In the past, public utilities have credited their deferred income tax accounts under the assumption that the 46 percent Federal corporate income tax rate (and in some cases, an even higher rate) would continue. Since the Federal corporate income tax rate has been reduced 12 percentage points, this assumption is no longer valid. To the extent that ratepayers have overprovided for expected future tax liabilities in a jurisdictional company's deferred income tax accounts in the past, ratepayers are entitled to reductions in future rates of the amounts now determined to be in excess of a jurisdictional company's future income tax needs through some form of amortization plan.

The Tax Reform Act does not change the Internal Revenue Code requirements regarding normalization of the benefits of accelerated depreciation and investment tax credits,¹⁴ it does place restrictions on how rapidly certain of these overfunded deferred tax amounts can be returned to customers.¹⁵ However, the Tax Reform Act does not restrict how rapidly any excess can be flowed back that is related to previous tax rate reductions or to timing differences other than those required to be normalized by sections 167 and 168 of the Internal Revenue Code. For example, any excess deferred tax amounts associated with construction period interest, payroll taxes, property taxes, and pension and employee benefits are not subject to a statutory restriction on how rapidly such amounts may be returned to customers.

The Commission intends to require adherence to the ratemaking requirements of Order Nos. 144 and 144-A, which were codified in § 35.25 and § 154.63a of the Commission's regulations.¹⁶ These requirements provide an appropriate treatment of any excess accruals that are created by the reduction in tax rates provided by the Tax Reform Act. Under these requirements a jurisdictional company would be required to propose a plan to return any excess accruals at the time it files for a rate change other than the

abbreviated rate change filing proposed in this Notice. This would create an opportunity for the staff, the jurisdictional company, and its customers to focus on the varied and perhaps unique circumstances related to the obligations and needs of each system including adherence to the Internal Revenue Code requirements that jurisdictional companies use the "average rate assumption method." Jurisdictional companies would not receive a windfall from this approach, since the excess accruals are used as a rate base deduction until the excess is returned to customers. In addition, jurisdictional companies should continue to record an amount to the deferred tax accounts equal to the amortization amount adopted and being collected through previously approved plans of recovery of deferred tax deficiencies (*i.e.*, South Georgia amortization amounts) until a new plan is approved in a future rate proceeding. Unless otherwise permitted by a Commission order, jurisdictional companies should continue to record income tax accruals (both current and deferred) through use of the 46 percent Federal corporation income tax rate until June 30, 1987. Therefore, a 34 percent Federal corporate income tax rate should be used.

B. Need For a Generic Approach For Public Utilities

This Notice proposes generic rules that are only applicable to public utilities since public utility rate schedules do not generally have tax trackers and the Commission believes that the abbreviated filing provision proposed in this Notice will conserve the time and resources of both filing utilities and the Commission. Generic rules are not proposed for natural gas pipeline companies or oil pipelines for the following reasons.

For natural gas pipeline companies, most rates that these entities are permitted to charge will automatically be reduced as a result of the new tax law. Specifically, language was included in the settled rate cases of some of the major natural gas pipeline companies that requires the filing of revised tariff sheets to reflect the change in tax rates. The other major natural gas pipeline companies have rate cases pending before the Commission that will permit the Commission to adjust these rates to reflect the change in tax rates, as appropriate. The remaining natural gas pipeline companies have language in their cost of service tariffs on file with the Commission that provides for the use of "actual tax," or similar language

that will require that these companies reflect the lower Federal corporate income tax rate in their rates. The Commission believes that any other changes in rates by natural gas pipeline companies due to the change in Federal corporate income tax rate is best handled on a case-by-case basis through investigations under section 5 of the Natural Gas Act due to the limited number of cases, if any, that remain.

The Commission has also decided not to propose generic rules applicable to oil pipelines. Due to the differing ratemaking methodologies used to set oil pipeline rates, the Commission believes that each carrier's books should be examined by Commission staff on a case-by-case basis in order to develop an appropriate methodology to reduce a carrier's rates to reflect the lower Federal corporate income tax rate and to refund any overfunded deferred taxes, as necessary.

IV. Discussion

A. Voluntary Filing

The Commission believes that the Federal corporate income tax rate decrease mandated by the Tax Reform Act of 1986 may result in significant overcollections by a public utility after July 1, 1987, if the public utility fails to adjust its rates to reflect this decrease. For this reason, the Commission is proposing to institute a procedure to encourage public utilities to voluntarily file rate reductions with the Commission under section 205 of the Federal Power Act, to take effect as of July 1, 1987. The Commission is considering several alternative approaches to implement this procedure. The primary option under consideration, would allow a public utility to adjust its rates (if such rates were based upon a test period cost of service filing) pursuant to an abbreviated formulary procedure to reflect the decrease in the Federal corporate income tax rate. Another option under consideration is whether the Commission should adopt a generically-determined, fixed percentage reduction to the demand charge component of a public utility's existing rate.

The proposed voluntary filing procedure may not be used by a public utility if it has a rate case pending before the Commission in which the change in Federal corporate income tax rate may be reflected, provided that the effective date of the rates at issue will be not later than July 1, 1987; if it has an accepted tariff that provides for automatic adjustment of its rates to reflect the change in the Federal

¹⁴I.R.C. Sections 167 and 168 (1982).

¹⁵The Act requires that the excess deferred taxes are not to be flowed back to ratepayers more quickly than permitted by use of the "average rate assumption method." Tax Reform Act of 1986, Pub. L. No. 99-514, section 203(e)(2)(B), 100 Stat. 2146 (1986). The "average rate assumption method" effectively returns the excess deferred taxes over the remaining service life of the asset.

¹⁶Ratemaking requirements for oil pipelines also employ a normalization approach. See Williams Pipe Line Company, 31 FERC ¶ 61,377 (June 28, 1985).

corporate income tax rate; or if it has rates in effect which already reflect the reduced Federal corporate income tax rate. Moreover, where the public utility wishes to reflect in its rates all of the other tax changes occasioned by the Tax Reform Act of 1986, or changes in other cost elements, it may not use the abbreviated filing procedure proposed in this Notice, but must file a general rate case under sections 205 or 206 of the Federal Power Act, as appropriate.¹⁷ Similarly, formula rates may not be adjusted pursuant to the abbreviated procedures described in the proposed rule.

1. The Formulary Approach

Under the primary option, the Commission is proposing a formula which a public utility would use to adjust the tax allowance component of its cost of service in this abbreviated procedure. The formula is intended to adjust the income tax component of a public utility's rates on file to reflect the reduction in the Federal corporate income tax rate. A separate calculation must be made for each type of service offered by the public utility and for each individual customer group thereunder. The Commission proposes the following formula to reduce rates to reflect the change in the corporate income tax rate:

$$K = \frac{D - D(E/F)}{I}$$

Where:

D=Income taxes allowable included in rates in effect on the date that the change in Federal corporate income tax rate becomes effective

E=Income tax factor using the new Federal corporate income tax rate. This is computed by the following formula:
composite marginal income tax rate divided by 1 - composite marginal income tax rate.

F=Income tax factor using the old Federal corporate income tax rate. This is computed by the same formula used for determining E.

I=Billing units from rate application docket upon which the rates that are in effect are based. Absent extraordinary circumstances a public utility shall use demand billing units. This information is usually available in Statement BG of the rate application and/or settlement or compliance documents.

K=Required rate reduction per billing demand unit.

This formula may be broken down into the following four-step process:

$$(1) A \times \frac{B}{C} = D$$

$$(2) D \times \frac{E}{F} = G$$

$$(3) D - G = H$$

$$(4) \frac{H}{I} = K$$

Where:

A=Income taxes allowable (exclusive of deferred tax make-up provisions, i.e. "South Georgia" provisions and investment tax credit amortizations) included in revenue requirements in a public utility's rate application docket upon which the rates in effect on the date the Federal corporate income tax rate change becomes effective were finally accepted or approved. This information is generally included in Statement BK or BL of the filing as revised after any summary dispositions where revised rates were required to be filed.

B=Revenue level in effect on the date the change in Federal corporate income tax rate becomes effective using test period billing determinants. This information is generally available from Statement BG of the rate application and/or settlement or compliance filing documents.

C=Revenue requirement from the rate application docket which includes A. This is generally included in Statement BK or BL of the filing.

G=Income taxes allowable at the new Federal corporate income tax rate.

H=Difference between income taxes allowable at the new Federal corporate income tax rate, and at the old Federal corporate income tax rate. This is the revenue reduction required to reflect the reduction in the Federal corporate income tax rate.

The proposed four-step formula is designed to adjust the income tax component of a public utility's filed rates to reflect the reduction in the Federal corporate income tax rate. The Commission proposes to use the data provided by a public utility in the rate application supporting its present rates to derive the appropriate rate reduction. As indicated previously, since a public utility's rates generally differ with the various types of service a public utility provides (such as transmission service, full requirements service, or partial requirements service) and for each customer group thereunder, a separate rate reduction calculation must be made for each type of service and each

customer group, using the proposed formula.

In the first step, the income tax allowable component (A) from a public utility's last rate application is multiplied by the ratio of (B) the test period revenues from the rates actually in effect on July 1, 1987 (Statement BG of the public utility's rate application) to (C) the test period revenue requirement reported by the public utility in its last application (Statement BK or BL of the public utility's rate application). The result (D) represents the presumed income tax allowable component currently included in a public utility's rate in effect on the date that the change in Federal corporate income tax rates becomes effective, and is based on the old Federal corporate income tax rate. The calculation recognizes that the public utility's current rate level may be designed to achieve test period revenues lower than the revenue requirement originally requested by the public utility in its rate application. The difference between generated rate levels and revenue requirement may be due to a variety of reasons including reductions in rate levels due to settlement agreements, voluntary reductions, Commission orders, and Commission opinions. For those rates that were determined by Commission opinion or equivalent order following a litigated proceeding, the income tax allowance, exclusive of deferred tax make-up provisions and investment tax credit amortizations, shall be used as (D) in the formula instead of using "A x (B/C)" as (D).

In the second step, the presumed income tax allowable component (D), the result of the first step of the formula, is multiplied by the ratio of (E) the income tax factor at the new Federal corporate income tax rate to (F) the income tax factor at the old Federal corporate income tax rate. The result (G) represents the presumed income tax allowable based on the new Federal corporate income tax rate.

In the third step of the proposed formula, the presumed income tax allowable component based on the new Federal corporate income tax rate (G) (derived in the second step of the formula) is subtracted from the presumed income tax allowable component based on the old Federal corporate income tax rate (D) (derived in the first step of the formula). The result (H) represents the revenue reduction presumed necessary to reflect the new Federal corporate income tax rate.

Finally, in the fourth step of the proposed formula, the revenue reduction

¹⁷16 U.S.C. 824d and 824e (1982).

figure (H) is divided by the demand billing units reported in the public utility's last rate application to determine the revenue reduction per unit of billing demand (K). Some adjustments to this aspect of the formula may be appropriate if, for example, the public utility's rate is entirely energy-based, i.e., on a per kilowatt-hour basis, or if the public utility's rate design incorporates unusual features. In the event that some deviation from the use of demand billing units is proposed, such deviation must be appropriately justified in the abbreviated filing. The Commission specifically seeks comment on whether application of this formula will accurately calculate the reduction in rates to reflect the change in the Federal corporate income tax rate. The Commission also seeks comments as to the appropriate circumstances under which exceptions to the use of demand billing units in the formula should be allowed.

2. Fixed Percentage Reduction

The Commission is also seeking comments upon an alternative approach whereby a public utility would be permitted to voluntarily reduce the demand charge component of the rate it currently has on file by a generally-determined fixed percentage. Based upon a selected sampling of eight recent rate applications, staff found that reducing the Federal corporate income tax rate from 46 to 34 percent resulted in a decrease in the nonvariable cost portion of revenue requirement ranging from five to eight percent. While there is some degree of imprecision involved in the application of a fixed percentage reduction, such an approach may be administratively more feasible and capable of implementation in a shorter period of time than other approaches to reflect the Federal corporate income tax rate reduction.

Comments are requested upon the fixed percentage reduction as an alternative to the formulary approach. The Commission also specifically requests comments upon the appropriate level of any fixed percentage reduction.

3. Other Filing Options

The Commission is requesting comments on any other filing options it should consider to encourage public utilities to voluntarily tender rate reductions based on the reduction in the Federal corporate income tax rate. The Commission is interested in comments on a wide range of options, and whether public utilities should be accorded multiple filing options, in order to allow rate reductions to take effect by July 1, 1987.

4. The Abbreviated Filing Requirements

The Commission is proposing filing requirements similar to those now imposed for rate schedule changes other than increases under § 35.13(a)(2)(ii) of the Commission's regulations.¹⁸ In particular, the proposed abbreviated filing procedure requires the same general information as required under existing regulations. In addition, public utilities will be required to file only that information necessary to apply the formula or fixed percentage reduction described above.

5. Miscellaneous

The Commission notes that public utilities filing under this abbreviated filing procedure must make the change in rate effect on the date that the change in the Federal corporate income tax rate becomes effective (July 1, 1987) and must file the change at least 30 days before that date to permit the Commission staff and the public utility's customers time to review the filing before it becomes effective. However, the Commission proposes that the only issues which may be raised concerning this filing will be limited to whether the public utility is eligible to use the abbreviated filing procedure, and whether it applied the proposed formula or fixed percentage reduction properly. Under this proposal, any other issues raised will be served from the proceeding and treated as a separate complaint under section 206 of the Federal Power Act.¹⁹ The Commission specifically requests comments on these proposals.

The proposed regulations provide that before the date on which a change in the Federal corporate income tax rate becomes effective certain public utilities may adjust their rates to reflect only the decrease in the Federal corporate income tax rate, using the formula provided by the Commission in proposed § 35.27. Thus revised rates, adjusted to reflect the recent change in Federal corporate income tax rate, must be filed with the Commission by June 1, 1987, and must be proposed to become effective no later than July 1, 1987. If the public utility believes that its rates should reflect changes in costs other than those relating to the change in the Federal corporate income tax rate, the public utility is, of course, free to file a general rate case pursuant to sections 205 or 206 of the Federal Power Act, as appropriate.²⁰ The Commission intends

that if public utilities fail to make a filing to reduce their rates at least 30 days before the change in Federal corporate income tax rate becomes effective, those public utilities may be required to show cause, pursuant to section 206 of the Federal Power Act, why their current, unadjusted rate levels are just and reasonable.

B. Show Cause Proceedings

Under section 206 of the Federal Power Act,²¹ the Commission has the authority to investigate a public utility's rates to determine if they are just and reasonable. And, if the Commission makes a finding that such rates are unjust and unreasonable, the Federal Power Act provides further, that the Commission must adjust the public utility's rates to a just and reasonable level.²² The Commission is concerned that if a public utility fails to voluntarily adjust its currently effective rates to reflect the decrease in the Federal corporate income tax rate by July 1, 1987, such rates may constitute unjust and unreasonable rates under the Federal Power Act. For this reason, the Commission may institute show cause proceedings to investigate whether or not a public utility's rates are, in fact, excessive. Such an investigation would not be limited to issues related to the Tax Reform Act of 1986.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires Federal agencies to consider whether the rule, if promulgated, will have a "significant economic impact on a substantial number of small entities."²³ Nearly all of the jurisdictional utilities which may comply with the rule proposed here are too large to be considered "small entities" within the meaning of the Act.²⁴ Also, the Commission considers this proposed rule to be a voluntary procedure which public utilities may choose to use to reduce their rates. The Commission believes that this rule will be beneficial to public utilities by permitting these public utilities to revise their rates to reflect the change in the Federal corporate income tax rate without affecting other components of the rate. Since the impact on small entities affected by this rule is expected to be beneficial, the Commission does not believe the economic impact will be "significant" within the meaning of the RFA. The Commission certifies, therefore, that this rule, if promulgated,

¹⁸ 18 CFR 35.13(a)(2)(ii) (1986).

¹⁹ 16 U.S.C. 824(e) (1982).

²⁰ 16 U.S.C. 824d and 824e (1982).

²¹ 16 U.S.C. 824(e) (1982).

²² *Id.*

²³ 5 U.S.C. 601-612 (1982).

will not have a significant economic effect on a substantial number of small entities.

VI. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) ²⁴ and the Office of Management and Budget's (OMB) regulations ²⁵ require that OMB approve certain information collection requirements imposed by agency rule. The information collection provisions in this NOPR are being submitted to the Office of Management and Budget (OMB) for its approval. Interested persons can obtain information on the information collection provisions by contacting the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 (Attention: Ellen Brown (202) 357-8272). Comments on the information collection provisions can be sent to the Office of Information and Regulatory Affairs of OMB, New Executive Office Building, Washington, DC 20503 (Attention: Desk Officer for the Federal Energy Regulatory Commission).

VII. Public Comment Procedure

The Commission invites interested persons to submit written data, views, and other information concerning matters set out in this Notice. All comments should be submitted to the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, and should refer to Docket No. RM87-4-000. An original and 14 copies must be filed. Copies must be received by the Commission no later than April 20, 1987.

All comments will be placed in the Commission's public file and will be available for public inspection during regular business hours at the Commission's Division of Public Information, Room 1000, 825 North Capitol Street, NE., Washington, DC 20426.

(Federal Power Act, 16 U.S.C. 792-828c (1982))

List of Subjects In 18 CFR Part 35

Electric power rates, Electric utilities, Reporting and recordkeeping requirements.

In consideration of the foregoing, the Commission proposes to amend Part 35, Title 18, Chapter 1, Code of Federal Regulations as set forth below.

By direction of the Commission.
Kenneth F. Plumb,
Secretary.

1. The authority citation for Part 35 continues to read as follows:

Authority: Federal Power Act, 16 U.S.C. 891-828c; Department of Energy Organization Act, 42 U.S.C. 7101-7352; Executive Order No. 12009, 3 CFR 142 (1978).

2. In § 35.13, paragraph (a)(2)(ii) is revised to read as follows:

§ 35.13 Filing of changes in rate schedules.

* * * * *

(a) *General rule.* * * *

(2) *Abbreviated filing requirements.* * * *

(ii)(A) For rate schedule changes other than rate increases. Except as provided in paragraph (a)(2)(ii)(B) of this section, any utility that files a rate schedule change that does not provide for a rate increase, or that provides for a rate increase that is based solely on change in delivery points, a change in delivery voltage, or a similar change in service, shall submit with its filing only the information required in paragraphs (b) and (c) of this section.

(B) Any utility that files a rate schedule change that provides for a rate increase or decrease under § 35.27 of this part must submit with its filing only the information required by § 35.27 of this part.

* * * * *

3. Section 35.27 is added to read as follows:

§ 35.27 Changes of rates relating changes in the Federal corporate income tax rate.

(a) *Purpose.* The abbreviated filing procedure and formula in this section are intended to permit a public utility to make an adjustment to its rates to reflect an increase or decrease in the Federal corporate income tax rate under the Internal Revenue Code. This abbreviated filing procedure and formula would be used by a public utility in lieu of a more comprehensive rate filing under § 35.13 concerning changes in rate schedules.

(b) *Applicability.* (1) Except as provided in paragraphs (b)(2) and (b)(3) of this section, a public utility may use the abbreviated filing procedure and formula in this section to adjust its rates to reflect an increase or decrease in the Federal corporate income tax rate under the Internal Revenue Code.

(2) If a public utility has a rate case currently pending before the Commission in which the change in Federal corporate income tax rate can be reflected, and the effective date of the rates at issue therein is on or before

the effective date of the change in the Federal corporate income tax rate, the public utility may not use this section to adjust its rates.

(3) If a public utility has a rate accepted for filing by the Commission that provides for the automatic adjustment of its rates to reflect, without prior hearing, increases or decreases in the Federal corporate income tax rate, it may not use this section to adjust its rates.

(c) Formula for rate adjustment to reflect change in Federal corporate income tax rate.

(1) For purposes of establishing a rate reduction designed to reflect the percentage decrease in the Federal corporate income tax rate, a public utility must use the following formula:

$$K = \frac{D - D(E/F)}{I}$$

where:

D=Income taxes allowable included in rates in effect on the date that the change in Federal corporate income tax rate becomes effective.

E=Income tax factor using the new Federal corporate income tax rate. This is computed by the following formula:
composite marginal income tax rate divided by 1—composite marginal income tax rate

F=Income tax factor using the old Federal corporate income tax rate. This is computed by the same formula used for determining E.

I=Billing units from rate application docket upon which the rates that are in effect are based. Absent extraordinary circumstances a public utility shall use demand billing units. This information is usually available in Statement BG of the rate application and/or settlement or compliance documents.

K=Required rate reduction per billing demand unit.

(2) A separate rate reduction calculation using this formula is required for each type of service a public utility provides and for each individual customers group thereunder.

(d) *Abbreviated filing requirements for rate schedule changes due to changes in tax rates.* Any public utility that files a rate schedule change providing for a rate increase or decrease that is based on a change in the Federal corporate income tax rate under the Internal Revenue Code, must submit with its filing only the information required in paragraphs (d)(1) and (d)(2) of this section.

(1) *General information.* Any public utility filing under this section must file the following general information:

²⁴ 44 U.S.C. 3501-3520 (1982).

²⁵ 5 CFR 1320.12 (1985).

(i) A list of documents submitted with the rate schedule change;

(ii) The date on which the public utility propose to make the rate schedule change effective;

(iii) The names and addresses of persons to whom a copy of the rate schedule change has been mailed;

(iv) A brief description of the rate schedule change;

(v) A statement of the reasons for the rate schedule change;

(vi) A showing that all requisite agreement to the rate schedule change, or to the filing of the rate schedule change including any agreement required by contract, has in fact been obtained;

(vii) A form of notice suitable for publication in the **Federal Register** in accordance with 35.8 of this part.

(2) *Information relating to the effect of the rate schedule change.* Any public utility filing under paragraph (d)(1) of this section must also file the following information or materials:

(i) A table or statement comparing sales and services and revenues from sales and services under the rate schedule to be superseded or supplemented and under the rate schedule change, by applying the components of each such rate schedule to the billing determinants for each class of service, for each customer, and for each delivery point or set of delivery points that constitutes a billing unit;

(A) For each of the twelve months immediately before and each of the twelve months immediately after the proposed effective date of the rate schedule change, and the total for each of the two twelve-month periods; and

(B)(1) If in the immediately preceding rate change filing the public utility filed Statements BG and BH under paragraph (h) of § 35.13 of this part for Period I, for each of the twelve months of Period I; and

(2) If in the immediately preceding rate change filing Period II is the test period, for each of the twelve months of Period II.

(ii) A comparison of the rate schedule change and the public utility's other rate of similar wholesale services.

(e) *Hearing issues.* The only issues that may be raised by Commission staff or any intervenor under the procedures established in this section will be whether or not the public utility may file under this section, whether or not the formula in § 35.17 has been properly applied, and whether or not the correct information was used in that formula. Any other issues raised will be severed from the proceeding and treated as a separate complaint under section 206 of the Federal Power Act.

(f) *Effective date.* (1) A public utility choosing to use the abbreviated filing procedure and formula contained in this section will be required to file its rate schedule change no later than 30 days prior to the date of the rate change will go into effect.

(2) A public utility choosing to use the abbreviated filing procedure and formula contained in this section to reflect the decrease in the Federal corporate income tax rate in the recently enacted Tax Reform Act of 1986 will be required to file its rate schedule change no later than 30 days prior to the date the rate change will go into effect. Rate changes reflecting the reduction in the Federal corporate income tax rate caused by the Tax Reform Act of 1986 must be proposed to become effective no later than July 1, 1987.

[FR Doc. 86-5894 Filed 3-18-87; 8:45 am]

BILLING CODE 6717-01-M

are 8:00 AM to 4:00 PM Monday through Friday, except holidays. Comments may also be hand-delivered to this address.

FOR FURTHER INFORMATION CONTACT:
LCDR Steven P. Mojonnier, USCG, C/O U.S. Coast Guard Captain of the Port, 2710 N. Harbor Drive, San Diego, CA 92101-1064, telephone (619) 293-5860.

SUPPLEMENTARY INFORMATION:
Interested persons are invited to participate in this rulemaking by submitting written views, data, or arguments. Persons submitting comments should include their names and addresses, identify this notice (COTP San Diego Docket 87-04) and the specific section of the proposal to which their comments apply, and give reasons for each comment. Receipts of comments will be acknowledged if a stamped, self-addressed postcard or envelope is enclosed.

The regulations may be changed in light of comments received. All comments received before the expiration of the comment period will be considered before final action is taken on this proposal. No public hearing is planned, but one may be held if written requests for a hearing are received and it is determined that the opportunity to make oral presentations will aid the rulemaking process.

Drafting information

The drafters of this notice are LCDR Steven P. Mojonnier, project officer for the Captain of the Port, and LCDR Joseph R. McFaul, project attorney, Eleventh Coast Guard District Legal Office.

Discussion of Proposed Regulation

The Commander, Naval Base, San Diego, and the Officer in Charge, Naval Auxiliary Landing Field, San Clemente Island, have requested that the Captain of the Port, San Diego, California establish a security zone in the area of Wilson Cove, San Clemente Island. This security zone would include the water area within 1.5 nautical miles (1.73 statute miles, 2.8 kilometers) of the shoreline of San Clemente Island from Wilson Cove North End Light (LLNR 2565) to Spruce Pier, approximately 4.1 nautical miles (4.7 statute miles, 7.65 kilometers) southeast of Wilson Cove North End Light. This action is taken at the request of the United States Navy and is needed to safeguard U.S. Naval vessels and property from sabotage or other subversive acts, accidents, criminal actions or other causes of a similar nature. Entry into this zone is prohibited unless authorized by the Captain of the Port, San Diego.

DATE: Comments on this regulation must be received on or before May 4, 1987.

ADDRESS: Comments should be mailed to U.S. Coast Guard Captain of the Port, 2710 N. Harbor Drive, San Diego, CA 92101-1064. The comments and other material referenced in this notice will be available for inspection and copying at the above address. Normal office hours

public or protection of the operation from compromise and interference. The Captain of the Port concurs with the need for this security zone. The security zone is needed to protect persons and property from sabotage or other subversive acts, accidents, criminal actions, or other causes of a similar nature, and to secure the interests of the United States.

This regulation is issued pursuant to 50 U.S.C. 191 as set out in the authority citation for all of Part 165.

Economic Assessment and Certification

These regulations are considered to be non-major under Executive Order 12291 on Federal Regulation and non-significant under Department of Transportation regulatory policies and procedures (44 FR 11034; 26 February 1979). The economic impact has been found to be so minimal that a full regulatory evaluation is unnecessary. The area within the zone is a small area outside the normal shipping channels. The only vessels normally using these waters are U.S. Naval vessels. There will be minimal effect on routine navigation.

Since the impact of these regulations is expected to be minimal, the Coast Guard certifies that they will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

Proposed Regulation

In consideration of the foregoing, the Coast Guard proposes to amend Part 165 of Title 33, Code of Federal Regulations as follows:

PART 165—[AMENDED]

1 The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1225 and 1231; 50 U.S.C. 191; 49 CFR 1.46 and 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 33 CFR 160.5.

2. In Part 165, a new § 165.1111 is added, to read as follows:

§ 165.1111 Security Zone: Wilson Cove, San Clemente Island, California.

(a) **Location:** The following area is a security zone: The water area adjacent to San Clemente Island, California within 1.5 nautical miles (1.73 statute miles, 2.8 kilometers) of the shoreline of San Clemente Island from Wilson Cove North End Light (LLNR 2565) to Spruce Pier, approximately 4.1 nautical miles (4.7 statute miles, 7.65 kilometers)

southeast of Wilson Cove North End Light, described as follows:

Starting at a point on the shoreline of San Clemente Island, California, in position 33°01'25.0" N, 118°33'43.0" W, for a place of beginning (point A), thence northeasterly to 33°02'11.0" N, 118°32'13.5" W, (point B), thence southeasterly to 32°58'40.5" N, 118°29'15.5" W, (point C), thence southwesterly to 32°57'54.0" N, 118°31'17.2" W (point D), thence northwesterly along the shoreline of San Clemente Island to the place of beginning.

(b) **Regulations:** In accordance with the general regulations in § 165.33 of this part, entry into the area of this zone is prohibited unless authorized by the Captain of the Port, San Diego, California. Section 165.33 also contains other general requirements.

Dated: March 8, 1987.

E.A. Harms,

Commander, U.S. Coast Guard, Captain of the Port, San Diego, California.

[FR Doc. 87-5966 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-14-M

33 CFR Part 165

[COTP San Diego Regulation 87-05]

Safety Zone Regulations; San Clemente Island, CA, Pacific Ocean

AGENCY: Coast Guard, DOT.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Coast Guard is proposing to establish a safety zone in the vicinity of West Cove, San Clemente Island, California, consisting of the water area bounded by the following coordinates and the shoreline of San Clemente Island:

Point A—33°01'38.0" N, 118°36'18.0" W
 Point B—33°01'11.0" N, 118°37'25.0" W
 Point C—33°00'00.0" N, 118°36'51.0" W
 Point D—33°00'00.0" N, 118°34'56.5" W

This action is taken at the request of the United States Navy and is needed to protect persons, vessels and property from hazards associated with naval equipment and operations located or conducted within the zone. Entry into this zone would be authorized, but anchoring, fishing, or other similar activities would be prohibited unless authorized by the Captain of the Port, San Diego. At certain times, entry into the zone would be prohibited unless authorized by the Captain of the Port, San Diego. Notice of these times would be provided by Coast Guard personnel in the zone.

DATE: Comments on this regulation must be received on or before May 4, 1987.

ADDRESS: Comments should be mailed to U.S. Coast Guard Captain of the Port,

2710 N. Harbor Drive, San Diego, CA 92101-1064. The comments and other material referenced in this notice will be available for inspection and copying at the above address. Normal office hours are 8:00 AM to 4:00 PM Monday through Friday, except holidays. Comments may also be hand-delivered to this address.

FOR FURTHER INFORMATION CONTACT:

LCDR Steven P. Mojonnier, USCG, C/O U.S. Coast Guard Captain of the Port, 2710 N. Harbor Drive, San Diego, CA 92101-1064, telephone (619) 293-5860.

SUPPLEMENTARY INFORMATION:

Interested persons are invited to participate in this rulemaking by submitting written views, data, or arguments. Persons submitting comments should include their names and addresses, identify this notice (COTP San Diego Docket 87-05) and the specific section of the proposal to which their comments apply, and give reasons for each comment. Receipts of comments will be acknowledged if a stamped, self-addressed postcard or envelope is enclosed.

The regulations may be changed in light of comments received. All comments received before the expiration of the comment period will be considered before final action is taken on this proposal. No public hearing is planned, but one may be held if written requests for a hearing are received and it is determined that the opportunity to make oral presentations will aid the rulemaking process.

Drafting information

The drafters of this notice are LCDR Steven P. Mojonnier, project officer for the Captain of the Port, and LCDR Joseph R. McFaul, project attorney, Eleventh Coast Guard District Legal Office.

Discussion of proposed regulation

The Commander, Naval Base San Diego, and the Officer in Charge, Naval Auxiliary Landing Field, San Clemente Island, have requested that the Captain of the Port, San Diego, California establish a safety zone in the area of West Cove, San Clemente Island. This safety zone would include the water area bounded by the following coordinates and the shoreline of San Clemente Island:

Point A—33°01'38.0" N, 118°36'18.0" W
 Point B—33°01'11.0" N, 118°37'25.0" W
 Point C—33°00'00.0" N, 118°36'51.0" W
 Point D—33°00'00.0" N, 118°34'56.5" W

This request was made to improve safety of naval facilities and operations at this location and to protect the public from hazardous naval operations. A

large number of hazardous naval operations are conducted routinely in this location, which are vital to national security and may endanger the public. In addition, naval equipment susceptible to damage from anchoring, fishing, and similar activities is located in the area of the zone. The safety zone is needed to protect persons, vessels, and property from hazards associated with naval operations in the zone. Entry into the zone would be permitted, but anchoring, fishing and other similar activities would be prohibited unless specifically authorized. In addition, entry into the zone would be prohibited at certain times, with notice of such times provided to the public by U.S. Coast Guard personnel in the zone.

This regulation is issued pursuant to 33 U.S.C. 1225 and 1231 as set out in the authority citation for all of Part 165.

Economic assessment and certification

These regulations are considered to be non-major under Executive Order 12291 on Federal Regulation and non-significant under Department of Transportation regulatory policies and procedures (44 FR 11034; 26 February 1979). The economic impact has been found to be so minimal that a full regulatory evaluation is unnecessary. The area within the zone is a small area outside the normal shipping channels. A small number of private vessels uses these waters occasionally. Entry to the zone will be prohibited infrequently. There will be minimal effect on routine navigation.

Since the impact of these regulations is expected to be minimal, the Coast Guard certifies that they will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

Proposed regulation

In consideration of the foregoing, the Coast Guard proposes to amend Part 165 of Title 33, Code of Federal Regulations as follows:

PART 165—[AMENDED]

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1225 and 1231; 50 U.S.C. 191; 49 CFR 1.46 and 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 33 CFR 160.5.

2. In Part 165, a new § 165.1112 is added, to read as follows:

§ 165.1112 Safety Zone: West Cove, San Clemente Island, California.

(a) **Location:** The following area is a safety zone: The water area of adjacent to San Clemente Island, California bounded by the following coordinates and the shoreline of San Clemente Island:

Point A—33°01'38.0" N, 118°36'18.0" W,
Point B—33°01'11.0" N, 118°37'25.0" W,
Point C—33°00'00.0" N, 118°36'51.0" W,
Point D—33°00'00.0" N, 118°34'56.5" W.

(b) **Regulations.** (1) accordance with the general regulations in § 165.33 of this part, entry into the area of this zone is permitted, but anchoring, fishing, and other similar activities are prohibited unless authorized by the Captain of the Port, San Diego, California.

(2) Entry into the area of this zone will be prohibited at certain times. U.S. Coast Guard personnel in the zone will provide notification to the public of the times when entry into the zone is prohibited.

(3) Section 165.33 also contains other general requirements.

Dated: March 6, 1987.

E. A. Harmes,

Commander, U.S. Coast Guard, Captain of the Port, San Diego, California.

[FR Doc. 87-5967 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-14-M

VETERANS ADMINISTRATION

38 CFR Part 1

Release of Veterans Administration (VA) List of Names and Addresses and Penalty Procedures for Unauthorized Use

AGENCY: Veterans Administration.

ACTION: Proposed regulatory amendments.

SUMMARY: The Veterans Administration (VA) is amending the existing regulations concerning VA lists of names and addresses and is also proposing administrative procedures to use when these lists are used for purposes not authorized by law. This action results from the need to amend the regulations to reflect current procedures, organizational changes, and concern expressed by veterans and some service organizations regarding unsolicited mail. The proposed regulatory amendments will allow the VA to enforce its statutory duty to protect the privacy of information concerning veterans and their dependents, establish procedures to suspend recipients who misuse VA names and addresses lists of veterans/

dependents, and give advance notice to recipients of what constitutes an authorized/unauthorized use of veterans/dependents names and addresses lists, thereby protecting the due process rights of any recipient before penalties are enforced.

DATES: Comments must be received on or before April 20, 1987. It is proposed that the effective date be upon final approval.

ADDRESSES: Interested persons are invited to submit written comments, suggestions, or objections regarding these changes to the Administrator of Veterans Affairs (271A), Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420. All written comments received will be available for public inspection only in the Veterans Services Unit, Room 132, at the above address between the hours of 8 a.m. and 4:30 p.m. Monday through Friday (except holidays) until April 30, 1987.

FOR FURTHER INFORMATION CONTACT: LaVerne Butler (202) 233-2545.

SUPPLEMENTARY INFORMATION: Under 39 CFR 1.519, the VA is authorized to release lists of names and addresses of veterans/dependents to any organization that makes written application to the VA and meets the provisions of 38 CFR 1.519 (a)(1) through (a)(8) and 38 U.S.C. 3301(f). These proposed regulatory amendments will establish the administrative procedures to be followed when it has been alleged that a recipient of a VA names and addresses list of veterans/dependents has made an unauthorized use of the list. They will also provide for uniform penalties the Agency may impose if the allegation is substantiated, inform recipients of the proper usage of VA names and addresses lists of veterans/dependents and ensure recipients of their due process under the law.

The VA has received numerous complaints and mail samples from veterans and several service organizations concerning unsolicited mail containing subject matter that is in violation of 38 U.S.C. 3301(f). At the present time, section 3301(f) has established criminal penalties for the misuse of veterans/dependents names and addresses. Because of the concern expressed by veterans and several service organizations, and rather than rely solely on criminal prosecution by the Department of Justice, it is important that the VA establish internal procedures to ensure the confidentiality of veterans/dependents records.

The Administrator certifies that these regulations, if promulgated, will not have a significant economic impact on a

substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601 through 612. Only a few entities legally may receive a list of veterans names and addresses from the VA under 38 U.S.C. 3301(f)(1) and only a few of these recipients would be considered small entities under 5 U.S.C. 601. Further, these regulations implement statutory bars on the misuse of the lists by the very small percentage of recipients who violate the law. Accordingly, pursuant to 5 U.S.C. 605(b), these flexibility analyses requirements of sections 603 and 604.

The Administrator has determined that these regulations are not a major rule as that term is defined by Executive Order 12291, Federal Regulation. The annual effect on the economy is less than \$100 million. These regulation amendments will not cause a major increase in costs or prices, nor will they have significant adverse effects on the economy.

Section 1.519(a) contains information collection requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, the Veterans Administration will submit a copy of these proposed regulatory amendments to the Office of Management and Budget (OMB) for its review. Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, Room 3002, New Executive Office Building, Washington, DC 20503; Attention: Allison Herron.

There is no Catalog of Federal Domestic Assistance Program number involved.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Freedom of Information, Government employees, Government property, Investigations, Privacy, Veterans, Veterans Administration.

These regulatory amendments are proposed under authority granted to the Administrator by 38 U.S.C. 210(c) and 3301(f).

Approved: February 11, 1987.

Thomas K. Turnage,
Administrator

38 CFR Part 1, *General*, is proposed to be amended by revising § 1.519 to read as follows:

§ 1.519 Lists of names and addresses.

(a) Any organization external to the VA, wanting a list of names and addresses of present or former personnel of the armed services and their dependents from the VA, must make written application to the Director,

Office of Information Management and Statistics (OIM&S). The application must:

(1) Clearly identify the type or category of names and addresses sought (e.g. Compensation and Pension (C&P), Education (EDU), Veterans Assistance Discharge System (VADS));

(2) Specify geographical restrictions in terms of entire states or particular zip codes in numerical order. Members of Congress are limited to the geographical area they currently represent;

(3) Furnish proof satisfactory to the VA that the organization seeking the list is a "nonprofit organization." Normally, evidence establishing that the organization has Federal tax exempt status in accordance with the provisions of 26 U.S.C. 501 or is a governmental body or institution will be accepted as satisfying these criteria;

(4) Contain a statement clearly setting forth:

(i) The purpose for which the list is sought. Use of a VA name and address list must be for a purpose which is essentially related to title 38, United States Code, veterans programs and benefits matters. The purpose of this authority is to aid in the dissemination of benefits information uniquely of interest to veterans and their dependents;

(ii) Establish how such purpose is an authorized purpose under Title 38, United States Code, and this section (this must be clearly shown before a request is approved); or

(iii) Establish that the requester (qualified representative) is a criminal or civil law enforcement governmental agent or instrumentality charged under applicable law with the protection of the public health or safety, and that the names and addresses are necessary for a purpose authorized by law.

(5) Contain a statement certifying that the requester, and the requester's employees/representatives who will have access to the list(s), are aware of the penalty provisions of 38 U.S.C. 3301(f) and will not use the list(s) for any purpose other than that stated in the application;

(6) Provide a point of contact including name, office, title, area code and telephone number in the event that technical questions arise;

(7) Specify the type of output desired (magnetic tape, gummed labels, or printed list; only one type of output will be produced);

(8) Be signed by the organization head or Member of Congress (for Congressional requests only).

(b) The Director, OIM&S, with the concurrence of the General Counsel, is authorized to release lists of names and

addresses to organizations which have applied for such lists in accordance with paragraph (a) of this section if it is found that the purpose for which the organization desires the names and addresses is authorized under Title 38, United States Code, and this section. Lists of names and addresses authorized to be released pursuant to this paragraph shall not duplicate lists released to other elements, segments, or chapters of the same organization. All tapes released to requesters must be returned to the data processing center (DPC) within 30 days of receipt. If the tapes are not returned within the 30 day limitation, the responsible DPC will notify the requester that the tapes are overdue. Requests for extensions will be evaluated (approved/denied) by OIM&S with the concurrence of the Office of the General Counsel (OGC), Office of Information Systems and Telecommunications (OIS&T), and the systems manager responsible for the system involved. If the tapes are not returned after due notice, no new tapes will be released to a requester until the delinquent tapes are returned.

(c) If the list requested is one that the VA has previously compiled or created in the same format to carry out one or more of its basic program responsibilities and it is determined that it can be released, the list may be furnished without charge. For other types of lists, a charge will be made in accordance with the provisions of § 1.526(f) of this title. Payment is required in advance and may be made by check or money order made payable to the Veterans Administration. Purchase orders are not an acceptable form of payment.

(d) Upon denial of a request, the Director, OIM&S, will inform the requester in writing of the denial and the reasons therefor, and advise the organization that it may appeal the denial to the Administrator. In each instance of a denial of a request, the denial and the reasons therefor will be made a matter of record.

(e) Section 3301(f), Title 38, United States Code, provides that any requester, or requester's employees/representatives, who uses the names and addresses for any purpose other than one directly connected with the conduct of programs and the utilization of benefits under 38 U.S.C. shall be fined not more than \$5,000 in the case of the first offense and not more than \$20,000 in the case of the subsequent offenses. Any instance in which there is evidence of violation of these penalty provisions will be reported in accordance with § 14.560 of this chapter.

(f) **Unauthorized uses.** Any use of a list for a purpose not authorized under Title 38, United States Code, and this section is an unauthorized use. The following are unauthorized uses by a requester:

(1) Use of the list to solicit members, either by express invitation to join or by the inclusion of materials to be mailed back to become a member or to seek more information regarding membership;

(2) Use of the list to advise of goods or services for purchase, such as group insurance; or

(3) Use of the list in a manner not expressly approved by the VA.

(g) Based on the evidence of record that a requester made an unauthorized use of any list of veterans names and addresses, the VA will, apart from any criminal penalties provided for by 38 U.S.C. 3301(f), impose one of the following sanctions:

(1) For the first use adjudicated to be unauthorized, a warning and/or a suspension from receiving a list of veterans names and addresses for any period up to 1 year;

(2) For the first adjudicated unauthorized use occurring after an adjudication under paragraph (g)(1) of this section, a warning and/or a suspension from receiving a list of veterans names and addresses for any period up to 3 years; and

(3) For any adjudicated determination of a sale of a list, or receipt of commercial benefit from the use of the list, and for any adjudicated unauthorized use occurring after an adjudication under paragraph (g)(2) of this section, a mandatory suspension from receiving a list of veterans names and addresses for any period up to 5 years.

Any suspension imposed will begin when the Director, OIM&S, issues a decision. Any requester so suspended will receive credit for any time spent on suspension after the issuance of the initial notice of suspension.

(h) When the VA has received a complaint of an unauthorized use of a VA-supplied names and addresses list or becomes aware of a possible unauthorized use of a list by any other means, the matter will be referred to OIM&S which will refer it to the Office of the Inspector General (OIG) for investigation. After completing its investigation, the OIG will submit its report and findings to OIM&S, with a copy to the OGC. Based on its investigation, the OIG may refer the matter to the appropriate U.S. Attorney for consideration for criminal prosecution. The OIG will notify OIM&S of any referral to a U.S. Attorney and

the U.S. Attorney's decision concerning prosecutive action.

(i) If review by OIM&S indicates that the available evidence, if substantiated, would establish that an unauthorized use has occurred, and therefore, a suspension may be warranted, OIM&S will provide the requester by certified mail, return receipt requested, a notice stating:

(1) That the VA is proposing to suspend the requester from receiving VA names and addresses lists, and the reasons why;

(2) A summary of the evidence relied upon by the VA;

(3) That the requester has the right to an informal hearing on the merits of the matter upon request, at which hearing the requester would have the right to present written and oral evidence and argument. The requester must request a hearing in writing within 20 working days of the date of the receipt of the notice;

(4) That, regardless of whether a hearing is requested, the requester:

(i) Has the right to examine all the evidence the VA proposes to rely upon in deciding the matter; and

(ii) Has the right to respond in writing to the allegations, and to submit written evidence and arguments to challenge the accuracy of the VA's information and the correctness of the VA's conclusions drawn from the information.

(5) Notice that the requester is temporarily suspended from receiving any list of veterans names and addresses until an agency decision is made in the matter; and that the requester, within 10 working days of receipt of the notice, may ask in writing that the Director, OIM&S, for good cause shown, stay and temporary suspension (the written request for a stay of suspension must state the reasons why the requester believes the suspension should be stayed).

(6) That if the requester does not respond to the notice within 60 calendar days of the date of receipt of the notice, the VA will decide the matter based on the reasons stated in the notice.

(j) If OIM&S determines that suspension proceedings should be initiated against a requester, OIM&S shall inform the OIG of the intent to initiate proceedings, and of the status of the matter on administrative appeal or in court, if either is applicable.

(k) At the time the VA sends the notice of proposed suspension to the requester, the Director, OIM&S, shall:

(1) Appoint a presiding official who has not been involved in the investigation of the matter to conduct hearings or consider submissions in lieu of hearings, and who shall have the

powers necessary to conduct these proceedings, issue notices and establish how, when and where material may be submitted to the presiding official; and

(2) Appoint an agency representative who shall represent the VA at any hearings or in response to any submissions in lieu of hearing, and who shall present the evidence in support of the allegations of misuse of a list.

(l) If the requester asks for a hearing, upon receipt of the request:

(1) The presiding official shall notify the requester in writing of the date, time, and place of the hearing at least 10 working days in advance, and that:

(i) The requester may examine the evidence the VA intends to submit at the hearing, stating where, when and under what circumstances the requester may do so;

(ii) The requester may have a representative present at the hearing;

(iii) The hearing will be informal and the formal rules of evidence and procedure will not apply; the parties may question the witnesses and the only limitation on the admissibility of evidence is that it must be relevant and material to the issues involved in the hearing; and

(iv) Either party may make a contemporaneous record of the hearing at the party's expense.

(2) The presiding official shall conduct the hearing, at which testimony, evidence and arguments may be presented. The presiding official will determine the admissibility of anything presented at the hearing.

(3) Within 15 working days after the hearing or after any posthearing documents are scheduled to be submitted, the presiding official will make written findings and recommendations based on the evidence presented at the hearing and forward a copy to the Director, OIM&S, for review. The Director, OIM&S, will issue a written decision on the matter within 20 working days of the receipt of the written findings and recommendations. The Director's decision must state the grounds for the decision. If the Director finds that the requester has made an unauthorized use of a list of veterans names and addresses, the decision must state the penalty imposed on the requester, the reasons the penalty was imposed in addition to stating the reasons why the Director concluded that the requester has used the list for an unauthorized purpose.

(4) The decision must also inform the requester of a right to appeal the decision, in writing, to the Administrator within 20 working days of the date of the receipt of the decision. The Director

will mail a copy of the decision by certified mail to the requester and by internal mail to the VA representative.

(m) *Submission in lieu of hearing.* (1) If the requester has responded to the notice of intended VA action, but does not request a hearing, the presiding official will notify the requester by certified mail, return receipt requested, of when and where the requester may examine the evidence the VA intends to use in making its decision, and when and where the requester must file any written evidence or argument for consideration by the presiding official.

(2) The VA representative for the hearing will have 10 working days to respond to any material submitted to the presiding official by the requester before written findings and recommendations are made.

(3) The Director, OIM&S, will issue a written decision in accordance with the procedures set forth in paragraph (l)(3) of this section.

(n) *Decision without hearing or submission of written evidence.* If the requester does not ask for a hearing and elects not to submit written evidence within the time period stated in the notice of proposed VA action first sent to the requester by certified mail, the VA may impose any permissible penalty on the requester based upon evidence, a summary of which was provided in the notice. The Director, OIM&S, will issue a written decision in accordance with the procedures set forth in paragraph (l)(3) of this section.

(o) *Appeals.* (1) The Administrator or designee, upon written application by the requester, and for good cause shown, may suspend any penalties imposed pending the issuance of the Administrator's decision on the appeal.

(2) The appeal will be decided based upon the evidence of record within 20 working days of the receipt of the notice of appeal in the Office of the Administrator.

(3) The appellate decision will state the rationale, the penalties imposed on the requester, and advise of the right to apply to the Administrator for remission of the penalties imposed.

(4) After a requester is suspended from receiving a list of veterans names and addresses, the requester, after 6 months or 50 percent of the suspension period has passed, whichever is less, may ask the Administrator to remit the rest of the suspension period for good cause shown.

(p) *Lists of educationally disadvantaged veterans.* Lists of educationally disadvantaged veterans should be requested from the director of the nearest VA regional office. If the director of the regional office concerned

finds that the organization requesting the list(s) of names and addresses of educationally disadvantaged veterans is a nonprofit organization and operates an approved program of special secondary, remedial, preparatory or other educational or supplementary assistance to veterans as provided under Subchapter V, Chapter 34, Title 38, United States Code, then he or she may authorize the release of such names and addresses to the organization requesting them.

[38 U.S.C. 210(c), 301(f)]

[FR Doc. 87-5872 Filed 3-18-87; 8:45 am]

BILLING CODE 8320-01-M

POSTAL SERVICE

39 CFR Part 10

Proposed International Surface Air Lift Service to 57 Additional Countries and Revised Rate Schedules

AGENCY: Postal Service.

ACTION: Proposed rule.

SUMMARY: Pursuant to agreements with certain postal administrations, the Postal Service intends to begin International Surface Air Lift Service to certain new destination countries at postage rates indicated in the tables below. The Postal Service also proposed revised postal pound rates based on the network expansion and improved transportation and handling changes.

DATE: Comments must be received on or before April 18, 1987.

ADDRESS: Written comments should be directed to the General Manager, Rate

Development Division, Office of Rates, Rates and Classification Department, U.S. Postal Service, Washington, DC 20260-5350. Copies of all written comments will be available for public inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, in Room 8620, 475 L'Enfant Plaza West, SW., Washington, DC 20260-5350.

FOR FURTHER INFORMATION CONTACT:
Leon W. Perlman, [202] 268-2673.

SUPPLEMENTARY INFORMATION: The International Mail Manual is incorporated by reference in the Code of Federal Regulations, 39 CFR 10.1. Additions to the manual concerning the proposed new service, including the rate tables reproduced below, will be made in due course. Accordingly, although 39 U.S.C. 407 does not require advance notice and the opportunity for submission of comments on international service, and the provisions of the Administrative Procedure Act regarding proposed rulemaking [5 U.S.C. 553] do not apply [39 U.S.C. 410 [a]], the Postal Service invites interested persons to submit written data, views or arguments concerning the proposed expansion of the International Surface Air Lift Service at the rates indicated in the table below.

List of Subjects in 39 CFR Part 10

Postal Service, Foreign relations.

PART 10—[AMENDED]

The authority citation for Part 10 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 401, 404, 407, 408.

INTERNATIONAL SURFACE AIR LIFT SERVICE PROPOSED POSTAL POUND RATES

Groups	Full Service		Downship ¹	
	Regular	M-BAG	Regular	M-BAG
1		\$2.85	\$2.28	\$2.25
2		2.35	1.88	2.05
3		2.22	1.78	1.92
4		3.10	2.48	2.80
5		3.90	3.12	3.60

¹ For International Surface Air Lift Mail presented at the J.F. Kennedy airmail facility, Queens Borough, New York City, by the mailer.

INTERNATIONAL SURFACE AIR LIFT SERVICE RATE GROUPS

[New Destination Countries for: Rate Groups ²]

(1)	(2)	(3)	(4)	(5)
Algeria.....	NONE	NONE	NONE	Angola. Bahrain. Bangladesh. Benin. Burkina Faso.
Canary Islands				
Egypt.....				
Libya.....				
Morocco.....				

INTERNATIONAL SURFACE AIR LIFT SERVICE RATE GROUPS—Continued

[New Destination Countries for Rate Groups ²]

(1)	(2)	(3)	(4)	(5)
Tunisia.....				Burundi.
Turkey.....				Cameroon.
USSR.....				Central Africa Rep.

Congo.
Ethiopia.
Gabo.
Ghana.
Iran.
Iraq.
Israel.
Ivory Coast.
Jordan.
Kenya.
Kuwait.
Lebanon.
Liberia.
Madagascar.
Mali.
Mauritania.
Mauritius.
Mozambique.
Niger.
Oman.
Pakistan.
Qatar.
Reunion.
Rwanda.
Saudi Arabia.
Senegal.
Sierra Leone.
Somalia.
Sri Lanka.
Sudan.
Syria.
Tanzania.
Togo.
Uganda.
United Arab
Emirates.
Yemen, Peop.
Dem. Rep.
Yemen Arab.
Republic.
Zaire.
Zambia.
Zimbabwe.

² A list of the 67 current countries by rate group may be obtained by writing the Office of Marketing, Market Development Division, U.S.P.S. Headquarters, 475 L'Enfant Plaza West, SW., Washington, DC 20260-6331, or by calling that Division at [202] 268-2263.

An appropriate amendment to 39 CFR 10.3 to reflect these changes will be published when the final rule is adopted.

Fred Eggleston,

Assistant General Counsel, Legislative Division.

[FR Doc. 87-5859 Filed 3-18-87; 8:45 am]

BILLING CODE 7710-12-M

FEDERAL MARITIME COMMISSION

46 CFR Part 503

[Docket No. 87-5]

Implementation of Freedom of Information Reform Act

AGENCY: Federal Maritime Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Maritime Commission proposes to amend its Public Information regulations to incorporate the recent changes to the

Freedom of Information Act regarding requests for agency enforcement records and regarding establishment of fees to be charged for search, review and duplication of records in response to FOIA requests. The proposed rules follow the guidelines established by the Office of Management and Budget.

DATE: Comments due on or before March 8, 1987.

ADDRESS: Comments (Original and 20 copies) to: Joseph C. Polking, Secretary, Federal Maritime Commission, 1100 L Street NW., Washington, DC 20573. (202) 523-5725.

FOR FURTHER INFORMATION CONTACT: Joseph C. Polking, Secretary, Federal Maritime Commission, 100 L Street NW., Washington, DC 20573. (202) 523-5725.

SUPPLEMENTARY INFORMATION: On October 27, 1986, President Ronald Reagan signed into law the Anti-Drug Abuse Act of 1986, an omnibus piece of legislation which includes as sections 1801-04 of the law, the Freedom of Information Reform Act of 1986 (Reform Act). This legislation expands the law enforcement protections of the Freedom of Information Act (FOIA) and also modifies its fee and fee-waiver provisions. The new law enforcement provisions were effective immediately. The fee provisions will become effective on April 25, 1987. This 180-day delay was designed to permit the Office of Management and Budget (OMB) and affected agencies time to issue new guidelines and regulations governing them. OMB published proposed guidelines on January 16, 1987 (52 FR 1992).

The purpose of these proposed rules is to implement the above-referenced changes mandated by the Reform Act. Implementation of the changes will be through appropriate amendments of the Commission's current Public Information rules appearing in 46 CFR Part 503. The following is a section by section discussion of the proposed rule changes.

1. Section 503.35 Exceptions to availability of records. Paragraph (a)(7) of this section currently describes the circumstances under which "investigatory" records may be withheld by the Commission when responding to an FOIA request. Paragraph (a)(7) is being revised to recite verbatim the revised standard promulgated by the Reform Act. The general thrust of the revised standard is to clarify and broaden the scope of the exemptions on law enforcement records or information.

A new paragraph (c) is also being added to this section implementing subsection (a)(1) of the Reform Act, to

provide the agency the option of excluding from the requirements of the FOIA, law enforcement records involving a possible violation of criminal law, when there is reason to believe that the subject of the investigation is not aware of its pendency and disclosure of the existence of records could reasonably be expected to interfere with enforcement proceedings. The upshot of this provision is that the agency can, under appropriate circumstances, withhold acknowledgment even of the existence of an investigation.

2. Section 503.41 Policy and services available. This section is amended to incorporate a reference to the Reform Act and to conform the description of services available to the terminology used in the Reform Act and defined elsewhere in this rule. Clarification is also included regarding the nonapplicability of fees to requests for certain materials.

3. Section 503.43 Fees for services. Paragraphs (a) through (c) of this section are proposed to be revised to incorporate the new few requirements of the Reform Act. The rules closely follow the proposed guidelines of OMB. It is recognized that these guidelines are only "proposed" and are subject to revision. Any revisions to the guidelines will be taken into consideration by the Commission before issuance of final rules in this matter.

Paragraph (a) sets forth the definitions of terms used in the Reform Act and these rules. They follow almost verbatim the OMB guidelines.

Paragraph (b) sets forth general guidelines regarding collection of fees for search, duplication and review. It acknowledges that, to the extent fees are assessable, they reflect full direct costs as required by the Reform Act. This paragraph also describes the types of fees to be assessed according to the identity of the requester and sets forth restrictions and limitations for assessment of fees as required by the Reform Act.

Paragraph (c) sets forth the actual schedule of fees and charges for search, review, and duplication. As indicated above, these charges reflect full direct costs as required by the Reform Act and as defined by OMB guidelines. The fees for certification are merely restated from the current schedule and are not affected by the Reform Act.

The following information sets forth the basis upon which the charges for search, duplication and review of records are established. Direct labor costs were separated into two groups, (a) clerical/administrative, and (b) professional/executive. An average rate

per hour was developed for each group plus 16 percent of that rate to cover benefits. With one exception the computations exclude salaries of Commissioners and members of the Senior Executive Service (SES). The one exception relates to review of records to determine whether they are exempt from disclosure under § 503.35. Since this activity is performed by the Secretary of the Commission in his/her capacity as the Commission's FOIA Officer the full direct costs associated with that SES position are recovered.

List of Subjects in 46 CFR Part 503

Freedom of information.

PART 503—[AMENDED]

Therefore, for the reasons set forth above, Part 503 of Title 46 CFR is proposed to be amended as follows:

1. The authority citation for Part 503 continues to read as follows:

Authority: 5 U.S.C. 552, 552a, 552b, 553; E.O. 12356, 47 FR 14874, 15557, 3 CFR 1982 Comp., p. 167.

2. Section 503.35 is amended by revising paragraph (a)(7) and by adding a new paragraph (c) to read as follows:

§ 503.35 Exceptions to availability of records.

(a) * * *

(7) Records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information:

- (i) Could reasonably be expected to interfere with enforcement proceedings;
- (ii) Would deprive a person of a right to a fair trial or an impartial adjudication;
- (iii) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(iv) Could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source;

(v) Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law; or

(iv) Could reasonably be expected to endanger the life or physical safety of any individual.

(c) Whenever a request is made which involves access to records described in paragraph (a)(7)(i) of this section and the investigation or proceeding involves a possible violation of criminal law; and there is reason to believe that the subject of the investigation or proceeding is not aware of its pendency, and disclosure of the existence of the records could reasonably be expected to interfere with enforcement proceedings, the Commission may, during only such time as that circumstance continues, treat the records as not subject to the requirements of 5 U.S.C. 552 and this subpart.

3. Section 503.41 is amended by revising the introductory text and paragraph (a) to read as follows:

§ 503.41 Policy and services available.

Pursuant to policies established by the Congress, the Government's costs for special services furnished to individuals or firms who request such services are to be recovered by the payment of fees (Act of August 31, 1951, 5 U.S.C. 140 and Freedom of Information Reform Act of 1986, October 27, 1986, 5 U.S.C. 552).

(a) Upon request, the following services are available upon the payment of the fees hereinafter prescribed; except that no fees shall be assessed for search, duplication or review in connection with requests for single copies of materials described in §§ 503.11 and 503.21:

- (1) Records/documents search,
- (2) Duplication of records/documents,
- (3) Review of records/documents,
- (4) Certification of copies of records/documents.

4. Section 503.43 is amended by revising paragraphs (a) through (c) to read as follows:

§ 503.43 Fees for services.

(a) **Definitions.** The following definitions apply to the terms when used in this subpart:

(1) "Search" means all time spent looking for material that is responsive to a request, including line-by-line identification of material within documents. Such activity is distinguished, however, from "review" or material in order to determine whether the material is exempt from disclosure. Searches may be done manually or by computer using existing programming.

(2) "Duplication" means the process of making a copy of a document necessary to respond to a Freedom of Information Act or other request. Such copies can take the form of paper or machine readable documentation (e.g., magnetic tape or disk), among others.

(3) "Review" means the process of examining documents located in response to a commercial use request to determine whether any portion of any document located is permitted to be withheld. It also includes processing any documents for disclosure, e.g., doing all that is necessary to excise them and otherwise prepare them for release. Review does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(4) "Commercial use request" means a request from or on behalf of one who seeks information for a use or purpose that is related to commerce, trade or profit as these phrases are commonly known or have been interpreted by the courts in the context of the Freedom of Information Act. In determining whether a requester properly belongs in this category, the agency will look first to the use to which a requester will put the documents requested. Where a requester does not explain a purpose, or where the explanation is insufficient, the agency may draw reasonable inferences from the identity of the requester and charge fees accordingly. Thus, for example, the agency would be entitled to presume that a document request written on corporate letterhead stationery that merely recites a list of the documents wanted is for a commercial use.

(5) "Educational institution" means an accredited institution of higher learning engaged in scholarly research.

(6) "Non-commercial scientific institution" means an independent non-profit institution whose purpose is to conduct scientific research.

(7) "Representative of the news media" means any representative of established news media outlets, i.e., any organization such as a television or radio station, or a newspaper or magazine of general circulation, or person working for such organization which regularly published information for dissemination to the general public whether electronically or in print.

"Freelance" journalists may be regarded as working for a news organization if they can demonstrate a solid basis for expecting publication through that organization, even though not actually employed by it.

(8) "Direct costs" means those expenditures which an agency actually incurs in searching for and duplicating (and in the case of commercial

requester, reviewing) documents to respond to a Freedom of Information Act request. Direct costs include, for example, the salary of the employee performing work (the basic rate of pay for the employee plus 16 percent of that rate to cover benefits) and the cost of operating duplicating machinery. Not included in direct costs are overhead expenses such as costs of space, and heating or lighting the facility in which the records are stored.

(b) *General.* (1) The basic fees set forth in paragraph (c) of this section provide for documents to be mailed with postage prepaid. If copy is to be transmitted by registered, certified, air, or special delivery mail, postage therefor will be added to the basic fee. Also, if special handling or packaging is required, costs thereof will be added to the basic fee.

(2) The fees for search, duplication and review set forth in paragraph (c) of this section reflect the full direct costs expected to be incurred by the agency for the service. Cost of search and review may be assessed even if it is determined that disclosure of the records is to be withheld. Requesters eligible for free search must reasonably describe the records sought. The following restrictions, limitations and guidelines apply to the assessment of such fees:

(i) For commercial use requesters, charges recovering full direct costs for search, review and duplication of records will be assessed.

(ii) For educational and non-commercial scientific institution requesters, no charge will be assessed for search or review of records. Charges recovering full direct costs for duplication of records will be assessed, excluding charges for the first 100 pages. To be eligible for inclusion in this category, requesters must show that the request is being made under the auspices of a qualifying institution and that the records are not sought for a commercial use, but are sought in furtherance of scholarly (if the request is from an educational institution) or scientific (if the request is from a non-commercial scientific institution) research.

(iii) For representative of the news media requesters, no charge will be assessed for search or review of records. Charges recovering full direct costs for duplication of records will be assessed, excluding charges for the first 100 pages.

(iv) For all other requesters, no charge will be assessed for review of records. Charges recovering full direct costs for search and duplication of records will be assessed excluding charges for the

first 100 pages of duplication and the first two hours of search time.

(v) No fee may be charged for search, review or duplication if the costs of routine collection and processing of the fee are likely to exceed the amount of the fee.

(vi) Documents shall be furnished without any charge or at a reduced charge if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(vii) Interest may be charged record requesters who fail to pay fees assessed. Assessment of interest may begin on the amount billed starting on the 31st day following the day on which the billing was sent. Interest will be at the rate prescribed in section 3717 of Title 31, United States Code.

(viii) Whenever it reasonably appears that a requester of records or a group of requesters is attempting to break a request down into a series of requests for the purpose of evading the assessment of fees, such requests will be aggregated and fees assessed accordingly.

(ix) Where a requester has previously failed to pay a fee charged in a timely fashion (i.e., within 30 days of the date of the billing), the requester will be required to pay the full amount owed plus any applicable interest as provided above, and to make an advance payment of the full amount of the estimated fee before the agency begins to process a new request or a pending request from that requester.

(x) Whenever action is taken under paragraphs (b)(2)(viii) and (b)(2)(ix) of this section, the administrative time limits prescribed in subsection (a)(6) of 5 U.S.C. 552 (i.e., 10 working days from receipt of initial requests and 20 working days from receipt of appeals from initial denial, plus permissible extensions of these time limits) will begin only after the Commission has received fee payments described above.

(c) *Charges for search, review, duplication and certification.* (1) Records search will be performed by Commission personnel at the following rates:

(i) Search will be performed by clerical/administrative personnel at a rate of \$11.00 per hour and by professional/executive personnel at a rate of \$23.00 per hour.

(ii) Minimum charge for record search is \$11.00.

(2) Charges for review of records to determine whether they are exempt

from disclosure under § 503.35 shall be assessed to recover full direct costs at the rate of \$38.00 per hour.

(3) Charges for duplication of records and documents will be assessed as follows, limited to size 8½" x 14" or smaller:

(i) If performed by requesting party, at the rate of five cents per page (one side).

(ii) By Commission personnel, at the rate of five cents per page (one side) plus \$11.00 per hour.

(iii) Minimum charge for copying is \$3.50.

(4) The certification and validation (with Federal Maritime Commission seal) of documents filed with or issued by the Commission will be available at \$5.00 for each certificate.

* * * * *

By the Commission.

Joseph C. Polking,
Secretary.

[FR Doc. 87-5883 Filed 3-18-87; 8:45 am]

BILLING CODE 6730-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1042

[Ex Parte No. MC-65 (Sub-No. 7)]

**Passenger Motor Carrier
Superhighway and Deviation Rules;
Withdrawal**

AGENCY: Interstate Commerce
Commission.

ACTION: Notice of proposed removal of
rules.

SUMMARY: The Commission recently discontinued a proceeding to liberalize the requirements for regular-route motor carriers of passengers to conduct operations over superhighways and deviation routes. Ex Parte No. MC-65 (Sub-No. 6) *Passenger Motor Carrier Superhighway and Deviation Rules* (not printed), served September 11, 1986, 51 FR 32500 September 12, 1987. The Commission determined that consideration of this proposal was unnecessary because the Bus Regulatory Reform Act of 1982 (Bus Act), Pub. L. 97-261, 96 Stat. 1102, substantially liberalized the entry for motor passenger carriers. The Bus Act's eased entry requirements and expanded licensing procedures allow passenger carriers the flexibility to pursue, and in most instances quickly obtain, operational changes. It appeared to remove the need for the Commission to retain a special procedure for obtaining motorbus superhighway and deviation operating authority separate from the new procedures adopted under the Bus Act.

Consistent with that decision, we now propose to repeal Subpart A of 49 CFR Part 1042 which contains Passenger Motor Carrier Superhighway and Deviation Rules. Subpart B of 49 CFR Part 1042 concerning motor carriers of property will not be affected by this proposal. By this notice the Commission solicits comments on the proposal.

DATE: Comments are due April 20, 1987.

ADDRESS: Send an original and 10 copies of comments referring to Ex Parte No. MC-65 (Sub-No. 7) to: Office of the Secretary, Case Control Branch,

Interstate Commerce Commission,
Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT:
Richard R. Hartley, 202-275-7786 or
Mark S. Shaffer, 202-275-7805.

SUPPLEMENTARY INFORMATION:

Additional information is contained in the Commission's full decision. To obtain a copy of the decision contact Office of the Secretary, Room 2215, Interstate Commerce Commission, Washington, DC 20423, or phone 202-275-7428.

This action does not appear to significantly affect either the quality of the human environment or conservation of energy resources.

Initial Regulatory Flexibility Analysis

We preliminarily conclude that the proposed elimination of the Passenger Motor Carrier Superhighway and Deviation Rules will not have a significant economic impact on a substantial number of small entities because carriers are now able to obtain expeditiously through the application procedures the same type of authority.

List of Subjects in 49 CFR Part 1042

Buses, Motor carriers.

Authority: 49 U.S.C. 10101, 10321, and 10922, and 5 U.S.C. 553.

Decided: March 10, 1987.

By the Commission, Chairman Gradison, Vice Chairman Lambole, Commissioners Sterrett, Andre, and Simmons.

Noreta R. McGee,
Secretary.

[FR Doc. 87-5917 Filed 3-18-87; 8:45 am]

BILLING CODE 7035-01-M

Notices

Federal Register

Vol. 52, No. 53

Thursday, March 19, 1987

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

State of Kansas Abandoned Mined Land Reclamation Program Payments; Determination of Primary Purpose of Amounts That May Be Excluded From Income

AGENCY: Office of the Secretary, USDA.

ACTION: Notice of determination.

SUMMARY: The Secretary of Agriculture has determined that all state cost-share payments or improvements made under the Kansas Abandoned Mined Land Reclamation Program are made primarily for the purpose of soil and water conservation, protecting or restoring the environment, improving forest, or providing a habitat for wildlife. This determination is in accordance with section 126(b) of the Internal Revenue Code of 1954, as amended by section 543 of the Revenue Act of 1978 and the Technical Corrections Act of 1979. The determination permits recipients of these payments to exclude them from gross income to the extent allowed by the Internal Revenue Service.

FOR FURTHER INFORMATION CONTACT: Dan Chargo, Abandoned Mined Program Administrator, 107 W. 11th, P.O. Box 1418, Pittsburgh, Kansas 66762, (316) 231-8615; or Director, Land Treatment Program Division, Soil Conservation Service, USDA, P.O. Box 2890, Washington, DC 20013, (202) 382-1870.

SUPPLEMENTARY INFORMATION: Section 126 of the Internal Revenue Code of 1954, 26 U.S.C. 126, as amended by the Revenue Act of 1978 and the Technical Corrections Act of 1979, provides that certain payments made to persons under state conservation programs may be excluded from the recipient's gross income for federal income tax purposes if the Secretary of Agriculture determines that payments are made

"primarily for the purpose of soil and water conservation, protecting or restoring the environment, improving forests, or providing a habitat for wildlife. . . ." The Secretary of Agriculture evaluates these conservation programs on the basis of criteria set forth in 7 CFR Part 14 and makes a "primary purpose" determination for the payments made under each program. Before there may be an exclusion, the Secretary of the Treasury must determine that the payments made to a person under these conservation programs do not substantially increase the annual income derived from the property benefited by the payments.

The Kansas Abandoned Mined Land Reclamation Program is authorized by the Mined Land Conservation and Reclamation Act of 1968 (KSA 49-401 *et seq.*). It is funded through grants from the Office of Surface Mining, U.S. Department of the Interior, to provide for the restoration or improvement of lands and waters of the state which have been adversely affected by past mining practices. Cost-share payments accomplish one or more of the following purposes:

(1) The protection of public health, safety, general welfare, and property from extreme danger of adverse effects of coal mining practices.

(2) The protection of public health, safety, and general welfare from adverse effects of coal mining practices.

(3) The restoration of land and water resources and the environment previously degraded by adverse effects of coal mining practices including measures for the conservation and development of soil, water, woodland, fish and wildlife, recreation resources, and agricultural productivity.

(4) Research and demonstration projects relating to the development of surface mining reclamation and water quality control program methods and techniques.

(5) The protection, repair, replacement, construction, or enhancement of public facilities such as utilities, roads, recreation and conservation facilities adversely affected by coal mining practices.

(6) The development of publicly owned land adversely affected by coal mining practices including land acquired as provided in the Surface Mining Control and Reclamation Act of 1977,

Pub. L. 95-87, as amended for recreation and historic purposes, conservation, and reclamation purposes and open space benefits.

Procedural Matters

The Department of Agriculture has classified this determination as "not major" in accordance with Executive Order 12291 and Secretary's Memorandum No. 1512-1. The Secretary has determined that these program provisions will not result in an annual effect on the economy of \$100 million or more; will not cause a major increase in cost to consumers, individuals, industries, government agencies, or geographic regions; and will not cause significant adverse effects of competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

A Kansas Abandoned Mined Land Reclamation Program "Primary Purpose Determination for Federal Tax Purposes," Record of Decision, has been prepared and is available upon request from the Director, Land Treatment Program Division, Soil Conservation Service, P.O. Box 2890, Washington, DC 20013, or Dan Cargo, Abandoned Mined Land Program Administrator, 107 W. 11th, P.O. Box 1418, Pittsburgh, Kansas 66762.

Determination

As required by section 126(b) of the Internal Revenue Code of 1954, as amended, I have examined the authorizing legislation, regulations, and operating procedures of the Kansas Abandoned Mined Reclamation Program. In accordance with the criteria set out in 7 CFR Part 14, I have determined that all cost-share payments made under this program are for soil conservation, protecting or restoring the environment, improving forests, or providing wildlife habitat. Subject to further determination by the Secretary of the Treasury, this determination permits payment recipients to exclude from gross income, for federal income tax purposes, all or part of such payments made under the Kansas Abandoned Mined Land Reclamation Program after July 1, 1986.

Signed at Washington, DC, on March 13, 1987.

Richard E. Lyng,
Secretary.

[FR Doc. 87-5971 Filed 3-18-87; 8:45 am]
BILLING CODE 3410-03-M

State of North Carolina Agriculture Cost-Share Program; Determination of Primary Purpose of Program Payments for Consideration as Excluded From Income

AGENCY: Office of the Secretary, USDA.
ACTION: Notice of determination.

SUMMARY: The Secretary of Agriculture has determined that all state cost-share payments made under the North Carolina Cost-Share Program pursuant to the Operating Procedures established according to S.L. 1984, c. 1034, s.s. 109-110, by the General Assembly of North Carolina have been made primarily for the purpose of soil and water conservation, protecting or restoring the environment, improving forests, or providing a habitat for wildlife. This determination is made in accordance with section 126(b) of the Internal Revenue Code of 1954, as amended by section 543 of the Revenue Act of 1978 and the Technical Corrections Act of 1979. The determination permits recipients of these payments to exclude them from gross income to the extent allowed by the Internal Revenue Service.

FOR FURTHER INFORMATION CONTACT:
William E. Austin, Director, Division of Soil and Water Conservation, Department of National Resources and Community Development, Post Office Box 27687, Raleigh, North Carolina 27611, (919) 733-2302, or Director, Land Treatment Program Division, Soil Conservation Service, USDA, Post Office Box 2890, Washington, DC 20013, (202) 382-1870.

SUPPLEMENTARY INFORMATION: Section 126 of the Internal Revenue Code of 1954, as amended by the Revenue Act of 1978 and the Technical Corrections Act of 1979, 26 U.S.C. 126, provides that certain payments made to persons under state conservation programs may be excluded from the recipient's gross income if certain determinations are made. The Secretary of Agriculture must determine whether payments made under a state program as described in section 126(a)(10) are "primarily for the purpose of soil and water conservation, protecting or restoring the environment, improving forests, or providing a habitat for wildlife . . ." In making this determination the Secretary of

Agriculture must evaluate each conservation program on the basis of critical set forth in 7 CFR Part 14.

The North Carolina Agriculture Cost-Share Program operates under operating procedures as established by the General Assembly of North Carolina (S.L. 1984, c. 1034, s.s. 109-110). The Program is funded by a stipulation appropriation in the Continuation Budget from the general fund that is made up of tax revenues such as sales tax, individual income tax, corporate tax, and franchise tax.

The purposes of the North Carolina Agriculture Cost-Share Program are to be achieved by entering into agreements with landowners to reduce the delivery of agricultural nonpoint source pollution, with emphasis on nutrient inputs, to important water supply and fishery resource water courses in North Carolina.

The North Carolina Soil and Water Conservation Commission administers the Cost-Share Program with direct staff support provided by the Division of Soil and Water Conservation, Department of Natural Resources and Community Development.

Soil and Water Conservation Districts (SWCDs) are responsible for local program implementation as stipulated in the operating procedures. The SWCDs sign agreements with landowners to install best management practices (BMPs) designed to prevent nonpoint source pollution. Under the agreement, the state will pay up to 75 percent of the average cost of implementing a system of BMPs. Landowners may provide in-kind labor, material, or equipment to reduce out-of-pocket costs. As a condition for cost-sharing, a landowner must agree to soil test treated lands to analyze animal wastes related to land application BMPs. The landowner also must sign an agreement to maintain the BMPs for the minimum life of the practices as listed in the operating procedures.

Cost-share payments are used to encourage landowners to install practices that will accomplish one or more of the following purposes:

1. Establish vegetative cover that will prevent erosion and the detachment of soil particles and associated nutrients.
2. Install animal waste treatment systems and manage fertilizer and waste application in a manner that will limit the availability of potential pollutants that could be transported to a stream system.

3. Construct terraces, grassed waterways, or other improvements that

will prevent the transport of pollutants to a stream system.

Procedural Matters

The Department of Agriculture has classified this determination as "not major" in accordance with Executive Order 12291 and Secretary's Memorandum No. 1512-1. The Secretary has determined that these program provisions will not result in an annual effect on the economy of \$100 million or more; will not cause a major increase in cost to consumers, individuals, industries, government agencies, or geographic regions; and will not cause significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

A North Carolina Agriculture Cost-Share Program, "Primary Purpose Determination for Federal Tax Purpose," Record of Decision, has been prepared and is available upon request from the Director, Land Treatment Program Division, Soil Conservation Service, Post Office Box 2890, Washington, DC 20013, Phone: (202) 382-1870, or William E. Austin, Director, Division of Soil and Water Conservation, Department of Natural Resources and Community Development, Post Office Box 27687, Raleigh, North Carolina 27611, Phone: (919) 733-2302.

Determination

As required by section 126(b) of the Internal Revenue Code of 1954, as amended, I have examined the authorizing legislation, regulation, and operating procedures of the North Carolina Agriculture Cost-Share Program. In accordance with the criteria set out in 7 CFR Part 14, I have determined that all cost-share payments made under this program are for soil and water conservation and protecting or restoring the environment. Subject to further determination by the Secretary of the Treasury, this determination permits payment recipients to exclude from gross income, for federal tax purposes, all or part of such payments made under the North Carolina Agriculture Cost-Share Program.

Signed at Washington, DC, on March 13, 1987.

Richard E. Lyng,
Secretary.

[FR Doc. 87-5973 Filed 3-18-87; 8:45 am]
BILLING CODE 3410-01-M

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board**

(Docket No. 2-87)

**Application for Foreign-Trade Subzone
Dow Chemical Plant, Midland,
Michigan; Antihistimine Production;
Flint, MI; Customs Port of Entry Area**

An application has been submitted to the Foreign-Trade Zones Board (the Board) pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400), by the City of Flint, Michigan, requesting special-purpose subzone procedures for a certain pharmaceutical product manufactured at Dow Chemical Company's Midland, Michigan plant, adjacent to the Saginaw/Bay City/Flint Customs port of entry. The City has a general-purpose foreign-trade zone application pending before the Board (Doc 11-85, 50 FR 21638, 5-28-85). The Dow subzone application was formally filed on February 24, 1987.

Dow Chemical Company, headquartered in Midland, Michigan, is the world's sixth largest producer of chemicals. It has 133 plants in 31 countries, with world-wide sales of some \$11 billion.

The proposed subzone would encompass Building 827 at Dow's Midland plant, "G" and 19th Streets, Midland, Michigan. While the plant produces a variety of chemical and pharmaceutical substances, this application requests subzone authority only for its production of Terfenadine, a non-sedating FDA-approved antihistimine [Alpha-[(4-(1,1-dimethylethyl) phenyl)-4-(hydroxydiphenyl methyl)-1-piperidine butanol]. The primary active ingredient is Terfenadone [1-(4-(1,1-dimethylethyl) phenyl)-4-(4-hydroxydiphenyl methyl) 1-piperidinyl 1-butanone], the only component which is sourced abroad. Some 20 percent of the finished product is exported.

Zone procedures would allow Dow to make its domestic Customs entries on the finished product, Terfenadine, which is duty-free under duty suspension legislation (TSUS 906.51). The duty rate on Terfenadone is 13.5 percent. Subzone procedures will help Dow's Midland plant compete for the production of this product with its overseas plants.

In accordance with the Board's regulations, an examiners committee has been appointed to investigate the application and report to the Board. The committee consists of: Dennis Puccinelli, Foreign-Trade Zones Staff, U.S. Department of Commerce, Washington,

DC 20230; William L. Morandini, District Director, U.S. Customs Service, North Central Region, 477 Michigan Ave., Detroit, MI 48226; and Colonel Robert F. Harris, District Engineer, U.S. Army District Detroit, P.O. Box 1027, Detroit, MI 48231.

Comments concerning the proposed subzone are invited in writing from interested parties. They should be addressed to the Board's Executive Secretary at the address below and postmarked on or before April 20, 1987.

A copy of the application is available for public inspection at each of the following locations:

U.S. Customs Service, Port Director's Office, P.O. Box 528, Bay City, MI 48707

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 1529, 14th and Pennsylvania Avenue, NW., Washington, DC 20230.

Dated: March 16, 1987.

*John J. Da Ponte, Jr.,
Executive Secretary.*

[FR Doc. 87-5978 Filed 3-18-87; 8:45 am]

BILLING CODE 3510-DS-M

International Trade Administration**Applications for Duty-Free Entry of Scientific Instruments; Thomas Jefferson University**

Pursuant to section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897; 15 CFR Part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with § 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, DC 20230. Applications may be examined between 8:30 a.m. and 5:00 p.m. in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket number: 87-113. Applicant: Thomas Jefferson University, 1025 Walnut Street, Philadelphia, PA 19107. Instrument: Electron Microscope, Model JEM-100CX. Manufacturer: JEOL Co., Ltd. Japan. Intended use: Electron microscopic examination of samples from the brain stem of experimental animals in order to determine the nature of the microcircuitry underlying respiratory and cardiovascular

regulation and the neuronal basis of hypertension. Application received by Commissioner of Customs: February 27, 1987.

Docket number: 87-115. Applicant: New Mexico State University, Las Cruces, NM 88003. Instrument: Electron Microscope, Model H-7000 with Accessories. Manufacturer: Hitachi Scientific Instruments, Japan. Intended use: The instrument will be used for analysis of electron bombarded specimens which will provide qualitative and quantitative information on the elemental composition of the specimen with high spatial resolution. In addition, the instrument will be used for the study of electron diffraction patterns produced by small crystals or very small selected areas of crystalline material. Research projects will range from basic studies in cellular physiology and biochemistry to the development of an efficient method of removing toxic contaminants from water. Application received by Commissioner of Customs: March 2, 1987.

Docket number: 87-116. Applicant: Purdue University, West Lafayette, IN 47907. Instrument: Electron Microscope, Model JEM-2000EX with Accessories. Manufacturer: JEOL Ltd., Japan. Intended use: The instrument is intended to be used for studies of solid state materials, in particular, metals, ceramics, semiconductors and new novel combinations. Experiments will be conducted to quantitatively characterize the atomic configurations and defects and to relate this information to the processing and/or physical properties. In addition, the instrument will be used to provide students with a fundamental background in transmission electron microscopy and associated analytical methods in the course MSE 640 Electron Microscopy and to provide training in independent research in various courses in M.S. and Ph.D. research. Application received by Commissioner of Customs: March 2, 1987.

Docket number: 87-117. Applicant: The Johns Hopkins University, Department of Earth and Planetary Sciences, Charles & 34th Streets, Baltimore, MD 21218. Instrument: Electron Probe X-Ray Microanalyzer, Model JXA-8600/3. Manufacturer: JEOL Limited, Japan. Intended use: The instrument will be used for x-ray analysis of material surfaces using wavelength dispersive and energy dispersive methods with a spatial resolution of 1-2 microns. The materials studied will include: metamorphic rocks, volcanic rocks, plutonic rocks, sedimentary rocks, and rocks from hydrothermal ore deposits. The

instrument will also be used to obtain chemical analyses of the crystalline and glassy products of phase equilibrium experiments and of mineral specimens later studied by transmission electron microscopy. In addition, the instrument will be used in courses to teach students how to obtain chemical analyses of geological materials. Application received by Commissioner of Customs: March 2, 1987.

Docket number: 87-118. Applicant: Massachusetts Institute of Technology, 77 Massachusetts Avenue, Cambridge, MA 02139. Instrument: Double Crystal X-ray Diffractometer System, Model 300. Manufacturer: Bede Scientific Instruments Ltd, United Kingdom. Intended use: The instrument is intended to be used for precision x-ray topography and x-ray double-crystal diffractometry experiments conducted in order to develop new nondestructive characterization techniques and to assist those active in fabricating these crystals. The instrument will also be used for educational purposes in the course 3.081 Materials Laboratory. Application received by Commission of Customs: March 2, 1987.

Docket number: 87-119. Applicant: University of Georgia, Complex Carbohydrate Research Center, Richard B. Russell Research Center, P.O. box 5677, Athens, GA 30613. Instrument: Superconducting Fourier NMR Spectrometer, Model AM 500. Manufacturer: Bruker Instruments Inc., West Germany. Intended use: Research in the following areas of chemistry:

(1) Conformational analysis of complex carbohydrates in solution,
(2) Primary structural investigations of complex carbohydrates,

(3) Study of interaction processes in which complex carbohydrates are involved,

(4) Development of new NMR methods dedicated to structural analysis of complex carbohydrates,

(5) Developing new methods for synthesizing complex oligosaccharides and

(6) Determining whether complex carbohydrates have been purified to homogeneity.

Application received by Commissioner of Customs: March 2, 1987.

Docket number: 87-120. Applicant: Argonne National Laboratory, 9700 South Cass Avenue, Argonne, IL 60439. Instrument: Mass Spectrometer, Model MS50TC with Accessories.

Manufacturer: Kratos Analytical, United Kingdom. Intended use: The instrument is intended to be used for the study of coals, separated coal macerals and reaction products produced from these

materials. The program objective is the elucidation of the micro and macro structure of coal macerals and the Argonne Premium Coal Samples. This information is then correlated with the chemical, thermal and biological reactivity of these substances.

Application received by Commissioner of Customs: March 3, 1987.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 87-5984 Filed 3-18-87; 8:45 am]

BILLING CODE 3510-DS-M

[C-337-601]

Countervailing Duty Order; Standard Carnations From Chile

AGENCY: Import Administration, International Trade Administration, Commerce.

ACTION: Notice.

SUMMARY: In its investigation, the U.S. Department of Commerce determined that standard carnations from Chile are being subsidized within the meaning of the countervailing duty law. In a separate investigation, the U.S. International Trade Commission (ITC) determined that imports of standard carnations from Chile are materially injuring a U.S. industry.

Therefore, based on these findings, a cash deposit of estimated countervailing duties of 12.25 percent *ad valorem* must be made on all entries, or withdrawals from warehouse, for consumption of standard carnations from Chile made on or after the date of publication of this countervailing duty order in the Federal Register.

EFFECTIVE DATE: March 18, 1987.

FOR FURTHER INFORMATION CONTACT:

Gary Taverman, Office of Investigations, or Richard Moreland, Office of Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: 202/377-0161 (Taverman) or 202/377-2786 (Moreland).

SUPPLEMENTARY INFORMATION: The products covered by this investigation are "standard carnations," as currently provided for in item 192.21 of the *Tariff Schedules of the United States* (TSUS).

In accordance with section 703 of the Tariff Act of 1930, as amended (the Act) (19 U.S.C. 1671b), on October 20, 1986, the Department published its negative preliminary determination that there was no reason to believe or suspect that manufacturers, producers, or exporters of standard carnations from Chile received benefits which constitute

subsidies within the meaning of the countervailing duty law (51 FR 21201). On January 27, 1987, the Department made its affirmative final determination that imports of the subject merchandise are being subsidized (52 FR 3313, February 3, 1987).

On March 5, 1987, in accordance with section 705(d) of the Act (19 U.S.C. 1671d(d)), the ITC notified the Department that subsidized imports of standard carnations from Chile materially injure a U.S. industry.

Therefore, in accordance with sections 708 and 751 of the Act (19 U.S.C. 1671e and 1675), the Department directs U.S. Customs officers to assess, upon further advice by the administering authority pursuant to sections 706(a)(1) and 751 of the Act (19 U.S.C. 1671e(a)(1) and 1675), countervailing duties equal to the amount of the net subsidy on all entries of standard carnations from Chile as described above. These countervailing duties will be assessed on all unliquidated entries of such standard carnations from Chile which are entered, or withdrawn from warehouse, for consumption, on or after the date of publication of the final determination on this case in the Federal Register.

On and after the date of publication of this notice, U.S. Customs officers must require, at the same time as importers would normally deposit estimated duties on this merchandise, a cash deposit of 12.25 percent *ad valorem* on all entries of standard carnations from Chile described in this notice.

This determination constitutes a countervailing duty order with respect to standard carnations from Chile pursuant to section 706 of the Act (19 U.S.C. 1671e(a)(1)) and § 355.36 of the Commerce Regulations (19 CFR 355.36). We have deleted from the Commerce Regulations Annex III of 19 CFR Part 355, which listed countervailing duty orders currently in effect. Instead, interested parties may contact the Central Records Unit, Room B-099, Import Administration, for copies of the updated list of orders currently in effect.

Notice of Review

In accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)), the Department hereby gives notice that, if requested, it will commence an administrative review of this order. For further information regarding this review, contact Richard Moreland at (202) 377-2786.

This notice is published in accordance with section 706 of the Act (19 U.S.C.

1671e) and § 355.36 of the Commerce Regulations (19 CFR 355.36).
Gilbert B. Kaplan,
Deputy Assistant Secretary for Import Administration.
 March 12, 1987.

[FR Doc. 87-5979 Filed 3-18-87; 8:45 am]
 BILLING CODE 3510-DS-M

Initiation of Countervailing Duty Administrative Review, Float Glass From Mexico

AGENCY: International Trade Administration/Import Administration Department of Commerce.

ACTION: Notice of initiation of countervailing duty administrative review.

SUMMARY: The Department of Commerce has received requests to conduct an administrative review of the suspension agreement on float glass from Mexico. In accordance with the Commerce Regulations, we are initiating this administrative review.

EFFECTIVE DATE: March 19, 1987.

FOR FURTHER INFORMATION CONTACT:
 Richard W. Moreland, Office of Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377-2786.

SUPPLEMENTARY INFORMATION: Background

On August 13, 1985, the Department of Commerce ("the Department") published in the *Federal Register* (50 FR 32556) a notice outlining the procedures for requesting administrative reviews. The Department has received timely requests, in accordance with § 355.10(a)(1) of the Commerce Regulations, for an administrative review of the suspension agreement on float glass from Mexico.

Initiation of Review

In accordance with § 335.10(c) of the Commerce Regulations, we are initiating an administrative review of the countervailing duty suspension agreement. We intend to issue the final results of this review no later than March 31, 1988.

Countervailing duty proceeding	Period to be reviewed
Unprocessed Float Glass from Mexico	1/1/86-12/31/86

This initiation and notice are in accordance with section 751(a) of the Tariff Act of 1930 (19 U.S.C. 1675(a)) and § 355.10(c) of the Commerce Regulations (19 CFR 355.10(c)).

Dated: March 14, 1987.

Gilbert B. Kaplan,
Deputy Assistant Secretary for Import Administration.
 [FR Doc. 87-5980 Filed 3-18-87; 8:45 am]
 BILLING CODE 3510-DS-M

Export Trade Certificate of Review, American Wood Chip Export Association

ACTION: Notice of Issuance of an Export Trade Certificate of Review, Application #86-00009.

SUMMARY: The Department of Commerce has issued an export trade certificate of review to American Wood Chip Export Association (a Webb-Pomerene association). This notice summarizes the conduct for which certification has been granted.

FOR FURTHER INFORMATION CONTACT:
 James V. Lacy, Director, Office of Export Trading Company Affairs, International Trade Administration, 202-377-5131.
 This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 ("the Act") (Pub. L. 97-290) authorizes the Secretary of Commerce to issue export trade certificates of review. The regulations implementing Title III are found at 15 CFR Part 325 (50 FR 1804, January 11, 1985).

The Office of Export Trading Company Affairs is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Department of Commerce to publish a summary of a certificate in the *Federal Register*. Under section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Conduct

Export Trade

Wood chips, sawdust, shavings and other wood fibers other than pulp (collectively herein, "wood chips").

Export Markets

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern

Mariana Islands and the Trust Territory of the Pacific Islands).

Export Trade Activities and Methods of Operation

AWCEA and its members may:

1. Discuss supply and demand for wood chips in export trade, including the quantities of wood chips desired by export customers, the supply of wood chips, based on domestic supply and demand, available for export trade, and anticipated export prices. AWCEA and its members may not discuss specific prices or quantities in specific domestic transactions by any member provided however that each member may, individually and on a confidential basis, furnish such information to AWCEA's secretary who will compute averages and trends regarding domestic prices and quantities for disclosure to the members. The secretary shall not disclose to any member the specific information furnished by any other member.

2. Discuss and/or agree upon the terms of export sales of wood chips to foreign buyers.

3. Discuss and/or agree upon export prices to be charged by AWCEA and/or the members for the sale of wood chips to foreign buyers.

4. Limit membership in AWCEA to companies which export wood chips.

5. Exclude from membership in AWCEA companies which are owned or controlled by, or are affiliated with, foreign individuals, corporations or governments.

Members

For purposes of this certificate, Sun Studs, Inc. and RLC Fibre Co., Inc. of Roseburg, Oregon; Medford Corporation of Medford, Oregon; Bohemia, Inc. of Eugene, Oregon; and North Coast Export Company (a Webb-Pomerene association) of Eureka, California are "members" within the meaning of § 325.2(1) of the Regulations.

A copy of each certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility, Room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

Dated: March 16, 1987.

James V. Lacy,
Director, Office of Export Trading Company Affairs.
 [FR Doc. 87-5981 Filed 3-18-87; 8:45 am]

BILLING CODE 3510-DR-M

Automated Manufacturing Equipment Technical Advisory Committee; Partially Closed Meeting

A meeting of the Automated Manufacturing Equipment Technical Advisory Committee will be held April 15, 1987, 9:30 a.m., Herbert C. Hoover Building, Room 6802, 14th Street and Constitution Avenue, NW., Washington, DC.

The Committee advises the Office of Technology and Policy Analysis with respect to technical questions which affect the level of export controls applicable to automated manufacturing equipment and related technology.

Agenda

1. Opening remarks by the Chairman.
2. Presentation of papers or comments by the public.
3. Discussion of numerically controlled machines.
4. Discussion of programmable controllers.
5. Request for certification of foreign availability.
6. TAC Committee communication.
7. Discussion of increased role of AMETAC in export cases.

Executive Session

8. Discussion of matters properly classified under Executive Order 12356, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The general session of the meeting will be open to the public and a limited number of seats will be available. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on January 10, 1986, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended by section 5(c) of the Government In The Sunshine Act, Pub. L. 94-409, that the matters to be discussed in the Executive Session should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552b(c)(1) and are properly classified under Executive Order 12356.

A copy of the Notice of Determination to close meetings or portions thereof is available for public inspection and copying in the Central Reference and Records Inspection Facility, Room 6628, U.S. Department of Commerce.

Telephone: (202) 377-4217. For further information or copies of the minutes contact Betty Ferrell at 202-377-4959.

Dated: March 16, 1987.

Margaret A. Cornejo,

Director, Technical Support Staff, Office of Technology and Policy Analysis.

[FR Doc. 87-5982 Filed 3-18-87; 8:45 am]

BILLING CODE 3510-DI-M

Electronic Instrumentation Technical Advisory Committee; Partially Closed Meeting

A meeting of the Electronic Instrumentation Technical Advisory Committee will be held April 7 and 8, 1987. On April 7, the meeting will convene on at 9:30 a.m. in Room 5230, Herbert C. Hoover Building, 14th & Constitution Avenue, NW., Washington, DC. The meeting will continue to its conclusion on April 8 in room 6802, the Herbert C. Hoover Building.

The Committee advises the Office of Technology and Policy Analysis with respect to technical questions which affect the level of export controls applicable to electronics and related equipment and technology.

General Session

1. Opening remarks by the Chairman.
2. Presentation of papers or comments by the public.
3. Continuation of discussion concerning the export controls on ECCN 1529A (Electronic Test Equipment).
4. Public comments are also invited on the following entries on the Commodity Control List (CCL): CCL 1522A—Lasers and Laser Systems.
- CCL 1531A—Frequency Synthesizers.
- CCL 1541A—Cathode Ray Tubes.
- CCL 1568A—Electromechanical Equipment.
- CCL 1572A—Recording and Reproducing Equipment.

Comments should consider the need for revision (strengthening, relaxation or decontrol) of the current regulations based on technological trends, foreign availability and national security. The Committee is also interested in proposals for revision to the People's Republic of China guidelines and G-COM regulations relating to these CCL numbers.

Executive Session

5. Discussion of matters properly classified under Executive Order 12356, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General session of the meeting will be open to the public and a limited

number of seats will be available. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting and can be directed to: Technical Support Staff, Office of Technology & Policy Analysis, Room 4073, 14th Street & Constitution Avenue, NW., Washington, DC 20230.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on January 10, 1986, pursuant to section 10(d) of the Government in the Sunshine Act, Pub. L. 94-409, that the matters to be discussed in the Executive Session should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552b(c)(1) and are properly classified under Executive Order 12356.

A copy of the Notice of Determination to close meetings or portions thereof is available for public inspection and copying in the Central Reference and Records Inspection Facility, Room 6628, U.S. Department of Commerce.

Telephone: 202-377-4217. For further information or copies of the minutes contact Betty A. Ferrell, 202/377-2583.

Dated: March 16, 1987.

Margaret A. Cornejo,

Director, Technical Support Staff, Office of Technology and Policy Analysis.

[FR Doc. 87-5983 Filed 3-18-87; 8:45 am]

BILLING CODE 3510-DT-M

CONSUMER PRODUCT SAFETY COMMISSION

Commission Priorities; Public Meeting

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of public meeting.

SUMMARY: The Commission will conduct a public meeting to obtain views from interested parties about priorities for Commission attention during fiscal year 1989. Participation by members of the public is invited. Written comments and oral presentations concerning Commission priorities will become part of the public record of this proceeding.

DATES: The meeting will begin at 10:00 a.m. on April 30, 1987. Requests from members of the public who desire to make oral presentations must be received by the Office of the Secretary not later than April 16, 1987. Persons desiring to make presentations at this

meeting must submit a written text or summary of their presentations no later than April 16, 1987. Written comments in lieu of oral presentations will be accepted until May 7, 1987.

ADDRESS: The meeting will be in room 456, 5401 Westbard Avenue, Bethesda, Maryland. Written comments should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207.

FOR FURTHER INFORMATION CONTACT: For information about the meeting or to request opportunity to make a presentation at the meeting, call or write Sheldon Butts, Deputy Secretary, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 492-6800.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to obtain views concerning projects and activities which should be given priority attention by the Commission during fiscal year 1989 from a wide range of interested parties including representatives of consumers; manufacturers, importers, distributors, and retailers of consumer products; members of the academic community; and representatives of health and safety agencies of state and local governments.

The Commission is charged by Congress with protection of the public from unreasonable risks of injury associated with consumer products. It administers and enforces: The Consumer Product Safety Act (15 U.S.C. 2051, *et seq.*); The Federal Hazardous Substances Act (15 U.S.C. 1261, *et seq.*); The Flammable Fabrics Act (15 U.S.C. 1191, *et seq.*); The Poison Prevention Packaging Act (15 U.S.C. 1471, *et seq.*); and The Refrigerator Safety Act (15 U.S.C. 1211 *et seq.*). Standards and regulations issued under those statutes are published in the Code of Federal Regulations, Title 16, Chapter II.

While the Commission has broad jurisdiction over products used by consumers in or around their homes, in schools, in recreation, and other settings, its staff and budget are limited. For these reasons, the Commission must concentrate its resources on the most serious hazards associated with consumer products within its jurisdiction in order to discharge its Congressional mandate effectively. Commission priorities are selected in accordance with the Commission policy governing establishment of priorities, published at 16 CFR 1009.8.

Interested parties who desire to make presentations at the meeting on April 30, 1987, should call or write Sheldon Butts, Deputy Secretary, Consumer Product Safety Commission, Washington, DC

20207; telephone (301) 492-6800, not later than April 16, 1987.

Presentations should be limited to approximately ten minutes. Persons desiring to make presentations must submit the written text or a summary of their presentations to the Office of the Secretary not later than April 16, 1987. The Commission reserves the right to impose further time limitations on all presentations and further restrictions to avoid duplication of presentations. The public meeting will begin at 10:00 a.m. on April 30, 1987, and will conclude the same day.

Written comments submitted in lieu of oral presentations should be received in the Office of the Secretary not later than May 7, 1987.

Dated: March 16, 1987.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 87-5892 Filed 3-18-87; 8:45 am]

BILLING CODE 6355-01-M

DEPARTMENT OF DEFENSE

Department of the Navy

Naval Research Advisory Committee; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app.), notice is hereby given that the Naval Research Advisory Committee Panel on U.S. Marine Corps Command and Control Systems Interoperability will meet on March 31 and April 1, 1987, at the Arlington Annex, Columbia Pike and South Gate Road, Arlington, Virginia. The meeting will commence at 9:00 A.M. and terminate at 3:30 P.M. on March 31 and April 1, 1987. All sessions of the meeting will be closed to the public.

The purpose of the meeting is to review interservice command and control systems requirements for naval forces in the near and mid-term, and identify future communications and command and control systems architecture features with a view toward improving interoperability. The agenda will include technical briefings and discussions addressing development programs and interoperability procedures. These briefings and discussions will contain classified information that is specifically authorized under criteria established by Executive order to be kept secret in the interest of national defense and is in fact properly classified pursuant to such Executive order. The classified and nonclassified matters to be discussed are so inextricably intertwined as to preclude opening any portion of the meeting. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of Title 5, United States Code.

For further information concerning this meeting contact: Commander T.C. Fritz, U.S. Navy, Office of Naval Research (Code 100N), 800 North Quincy Street, Arlington, VA 22217-5000, Telephone number (202) 696-4870.

Dated March 13, 1987.

Harold L. Stoller, Jr.,

Commander, JACC, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 87-5896 Filed 3-18-87; 8:45 am]

BILLING CODE 3810-AE-M

Naval Research Advisory Committee; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app.), notice is hereby given that the Naval Research Advisory Committee Panel on Laser-to-Submarine Communications will meet on April 7, 1987. The meeting will be held at the Pentagon, Washington, DC. The meeting will commence at 8:00 A.M. and terminate at 4:30 P.M. on April 7, 1987. All sessions of the meeting will be closed to the public.

The purpose of the meeting is to review and assess current laser technology programs with a view toward addressing communications problems pertaining to exploitation of the submarine over its full depth, range and speed capabilities. The agenda will include technical briefings and discussions addressing program plans and technology status. These briefings and discussions will contain classified information that is specifically authorized under criteria established by Executive order to be kept secret in the interest of national defense and is in fact properly classified pursuant to such Executive order. The classified and nonclassified matters to be discussed are so inextricably intertwined as to preclude opening any portion of the meeting. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of Title 5, United States Code.

For further information concerning this meeting contact: Commander T.C. Fritz, U.S. Navy, Office of Naval Research (Code 100N), 800 North Quincy

Street, Arlington, VA 22217-5000,
Telephone number (202) 696-4870.

Dated: March 13, 1987.

Harold L. Stoller, Jr.,
*Commander, JAGC, U.S. Navy, Federal
Register Liaison Officer.*

[FR Doc. 87-5897 Filed 3-18-87; 8:45 am]

BILLING CODE 3810-AE-M

DEPARTMENT OF EDUCATION

Education Appeal Board; List of Applications for Review Accepted for Hearing

AGENCY: Department of Education.

ACTION: Notice of applications for review accepted for hearing by education appeal board.

SUMMARY: This notice lists the applications for review accepted for hearing by the Education Appeal Board (the Board) between October 15, 1986, and February 13, 1987. The Chairman has prepared a summary about each appeal to help potential intervenors. In addition, the notice explains how interested third parties may intervene in proceedings before the Board.

FOR FURTHER INFORMATION CONTACT:

The Honorable Ernest C. Canellos,
Chairman, Education Appeal Board, 400 Maryland Avenue, S.W. (Room 1065, FOB-6), Washington, DC 20202.
Telephone: (202) 732-1756.

SUPPLEMENTARY INFORMATION: Under sections 451 through 454 of the General Education Provisions Act (20 U.S.C. 1234 *et seq.*), the Board has authority to conduct (1) audit appeal hearings, (2) withholding, termination, and cease and desist hearings initiated by the Secretary of Education (the Secretary), and (3) other proceedings designed by the Secretary as being within the jurisdiction of the Board.

The Secretary has designated the Board as having jurisdiction over appeal proceedings related to final audit determinations, the withholding or termination of funds, and cease and desist actions for most grant programs administered by the Department of Education (the Department). The Secretary also has designated the Board as having jurisdiction to conduct hearings concerning most Department-administered programs that involve (a) a determination that a grant is void, (b) the disapproval of a request for permission to incur an expenditure during the term of a grant, or (c) determinations regarding cost allocation plans or special rates negotiated with specified grantees.

Regulations governing Board jurisdiction and procedures were published in the *Federal Register* on May 18, 1981, at 46 FR 27304 (34 CFR Part 78).

Applications Accepted

Appeal of the State of Texas

[Docket No.: 23(223)86, ACN: 06-30016]

The State appealed a final letter of determination issued by the Assistant Secretary for Elementary and Secondary Education. The underlying audit reviewed the State's eligibility criteria applied to migrant children for whom funds were awarded under Chapter 1 of the Education Consolidation and Improvement Act of 1981 during fiscal year (FY) 1984.

The Assistant Secretary found that 52 out of a random sample of 350 students were ineligible to be counted as migratory for all or part of calendar year 1982, and that such ineligibility resulted in an overallocation of Federal funds for FY 1984.

The Department seeks a refund of \$7,093,008. The State disputes all liability.

Appeal of Illinois State Library

[Docket No.: 24(224)86, ACN: 05-65001]

The Library appealed a final letter of determination issued by the Assistant Secretary for Educational Research and Improvement. The audit reviewed the Library's administration of the Library Services and Construction Act (LSCA) programs for the period between July 1, 1982, and June 30, 1984.

The Assistant Secretary affirmed the findings of the audit report and concluded that the Library had improperly used LSCA funds to benefit non-public libraries.

The Department seeks a refund of \$1,976,961. The Library disputes all liability.

Appeal of the State of Wisconsin

[Docket No.: 25(225)86, ACN: 05-55001]

The State appealed a final letter of determination issued by the Acting Assistant Secretary for Vocational and Adult Education. The underlying audit reviewed the State's implementation of programs conducted by the Wisconsin Board of Vocational, Technical and Adult Education during the period July 1, 1981, through June 30, 1983.

The Acting Assistant Secretary sustained the auditor's conclusions that expenditures charged to vocational and adult education programs were improperly charged to Federal grants or used to offset disallowed expenditures

after expiration of the statutory period of availability.

The Department seeks a refund of \$316,275. The State disputes all liability.

Appeal of the State of New York

[Docket No. 26(226)86, ACN: 02-30028]

The State appealed a final letter of determination issued by the Acting Assistant Secretary for Vocational and Adult Education. The underlying audit reviewed "Selected Activities Funded under the Vocational Education Act" for the period July 1, 1979, through June 10, 1982.

The Acting Assistant Secretary partially sustained the auditor's report, concluding that the State had failed to document adequately salary costs, fringe benefits and indirect costs during FY 1981-1982.

The Department seeks a refund of \$6,436,081. The State disputes all liability and raises the statute of limitations as a bar to a portion of the claim.

Appeal of the State of California

[Docket No. 27(277)86, ACN: 09-50300]

The State appealed a final letter of determination issued by the Assistant Secretary for Special Education and Rehabilitative Services. The underlying audit reviewed expenditures made under Part B of the Education of the Handicapped Act (EHA-B) during FY 1979-1980.

The Assistant Secretary concluded that the State violated the recordkeeping provisions of EHA-B and failed to show that the transfer of expenditures and reallocation of funds occurred within the allowable statutory period.

The Department seeks a refund of \$9,092,692. The State disputes all liability.

Appeal of the Center for Educational Services, Inc.

[(MA) Docket No. 28(228)86, ACN: 01-40118]

The Center appealed a final letter of determination issued by the Grants and Contracts Service (GCS). The underlying audit reviewed the grant allocations to the Center for the period June 1, 1983, through May 31, 1984.

GCS disallowed certain costs associated with students' room and board, stipends, office communications, and indirect costs due to inadequate documentation and the excessive nature of the expenditures.

The Department seeks a refund of \$34,946. The Center disputes all liability and raises waiver as a defense.

Appeal of the Human Services Training and Research Council, Inc.

[(VA) Docket No. 29(229)86]

The Council appealed a final letter of determination issued by the Regional Commissioner, Rehabilitative Services Administration (RSA). The underlying grant review conducted by the Region III office of RSA and the Office of Inspector General examined the Rehabilitation Long-Term Training Program conducted between October 1, 1974, and August 31, 1983.

The Regional Commissioner disallowed specific indirect costs as excessive and unsupported by documentation.

The Department seeks a refund of \$22,666. The Council disputes all liability.

Appeal of the Government of Guam

[Docket No. 30(230)86, ACN: 09-41515]

The Government of Guam appealed a letter amendment to a final letter of determination issued by the Grants and Contracts Service (GCS). The underlying audit reviewed costs attributed to the Special Education for Handicapped Children Program conducted between October 1, 1981, and September 30, 1982.

GCS disallowed expenditures because of a discrepancy between the general ledger and the allotment ledger used to account for grant expenditures.

The Department seeks a refund of \$11,679. The Government of Guam disputes all liability.

Appeal of Brandeis University

[Docket No. 31(231)86, ACN: 01-40111]

Brandeis University appealed a final letter of determination issued by the Grants and Contracts Service (GCS). The underlying audit reviewed the Upward Bound Program conducted between June 1, 1980, and May 31, 1983.

GCS disallowed expenditures attributable to excessive or unapproved salary/fringe benefits, equipment purchases, telephone charges, and student stipends. Expenditures were also disallowed because of the failure to document costs properly.

The Department seeks a refund of \$422,960. Brandeis University disputes all liability.

Appeal of the State of Massachusetts

[Docket No. 33(233)86, ACN: 01-30017]

The State appealed a final letter of determination issued by the Assistant Secretary for Special Education and Rehabilitative Services. The underlying audit reviewed programs conducted under Part B of the Education of the Handicapped Act (EHA-B), and Title I

of the Elementary and Secondary Education Act (ESEA), between October 1, 1979, and September 30, 1982.

The Assistant Secretary concluded that the State failed to provide sufficient documentation to support the child count used to determine the FY 1982 EHA-B award. Because of the inadequate documentation, FY 1983 and FY 1984 awards were similarly disallowed. The Assistant Secretary also disallowed expenditures attributable to salaries because of the failure to maintain time distribution records.

The Department seeks a refund of \$568,530. The State disputes all liability.

Appeal of the State of New Jersey

[Docket No.: 34(234)86, ACN: 02-35011]

The State appealed a final letter of determination issued by the Assistant Secretary for Special Education and Rehabilitative Services. The underlying audit reviewed expenditures under Part B of the Education of the Handicapped Act (EHA-B) between July 1, 1979, and June 30, 1981.

The Assistant Secretary found that the FY 1981 EHA-B expenditures were inappropriately based upon a child count which exceeded the actual number of eligible handicapped children between the age of three and twenty-one.

The Department seeks a refund of \$171,135. The State disputes all liability.

Appeal of Seattle Community College

[Docket No.: 1(237)87, ACN: 10-62010]

The College appealed a final letter of determination issued by the Grants and Contracts Service (GCS). The underlying audit reviewed expenditures for Institutional Aid under Title III of the Higher Education Act, the Regional Education Program for Deaf and Hard of Hearing Students, the Interpreter Training Program, and the Regional Interpreter Training Program for the year ending June 30, 1984.

GCS disallowed costs attributable to salary/fringe benefits, equipment and indirect costs because of the lack of documentation. In some instances, the amount of the expenditures also accounted for the disallowance.

The Department seeks a refund of \$162,147. The College disputes all liability.

Intervention

Regulations in 34 CFR 78.43 provide that an interested person, group, or agency may file an application to the Board Chairman to intervene in an appeal before the Board.

An application to intervene must indicate to the satisfaction of the Board Chairman or, as appropriate, the Panel Chairperson, that the potential intervenor has an interest in, and information relevant to, the specific issues raised in the appeal. If an application to intervene is approved, the intervenor becomes a party to the proceedings.

Applications to intervene, or questions, should be addressed to the Board Chairman at the address provided above.

(20 U.S.C. 1234)

(Catalog of Federal Domestic Assistance No. not applicable)

Dated: March 13, 1987.

Peter R. Greer,*Deputy Under Secretary Intergovernmental and Interagency affairs.*

[FR Doc. 87-5903 Filed 3-18-87; 8:45 am]

BILLING CODE 4000-01-M

Invitation for Applications Under the School Construction in Areas Affected by Federal Activities Program for Fiscal Year 1987**Programmatic and Fiscal Information**

Notice is given that the Secretary of Education has established a cutoff date for the transmittal of applications for assistance under sections 5 and 9 of Pub. L. 81-815 based on increase periods ending June 1987 or June 1988. (An increase period is a period of four consecutive regular school years during which a school district has experienced a substantial increase in school membership as a result of new or increased Federal activities.) This cutoff date also applies to applications for assistance under section 14 or for supplemental assistance under Section 8 of Pub. L. 81-815. (Section 14 authorizes assistance for certain school districts which serve children residing on Indian lands, or which are significantly burdened by the presence of nontaxable Federal property. Section 8 authorizes assistance that supplements certain awards made under sections 5, 9, and 14 of Pub. L. 81-815.)

Approval of these applications is subject to availability of funds.

*Cutoff date for transmittal of applications: June 30, 1987.**Deadline date for intergovernmental review comments: Aug. 31, 1987.*

Applications available: Application forms may be obtained from the appropriate State educational agency which serves the applicant local educational agency.

Applicable regulations: (a) The regulations governing the School Construction Program (34 CFR Parts 218 and 221), and (b) The Education Department General Administrative Regulations (EDGAR) (34 CFR Parts 74, 75, 77, 78, and 79).

For information contact: Dr. Walter Steidle, School Construction Program, Division of Impact Aid, U.S. Department of Education, 400 Maryland Avenue SW, Room 2073, Washington, DC 20202-6272. Telephone: (202) 732-4663.

Program authority: 20 U.S.C. 631-645.

(Catalog of Federal Domestic Assistance No. 04.040 School Assistance in Federally Affected Areas—Construction)

Dated: March 16, 1987.

Lawrence F. Davenport,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 87-5904 Filed 3-18-87; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CI86-46-002]

Chevron U.S.A. Inc.; Application of Chevron, U.S.A. Inc. Amending Limited-term Abandonment and Sales Certificate

Take notice that on March 6, 1987, Chevron U.S.A. Inc. ("Chevron"), pursuant to the provisions of sections 4 and 7 of the Natural Gas Act ("NGA") (15 U.S.C. §§ 717c and 717f), and § 2.77 and Part 157 of the regulations of the Federal Energy Regulatory Commission ("Commission"), filed an application to amend its currently effective Limited-Term Abandonment authorization and blanket sales certificate in the above-captioned docket to (i) extend such authority for an additional three-year period, and (ii) expand such authority to permit limited-term abandonments and sales of all Natural Gas Policy Act categories of gas, including volumes whose maximum lawful price is at or below that established by section 109 of the NGPA.

It appears reasonable and consistent with the public interest in these cases to prescribe a period shorter than normal for the filing of protests and petitions to intervene. Therefore, any person desiring to be heard to or to make any protest with reference to said application should on or before March 23, 1987, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a petition to intervene or a protest in accordance with the

requirements of the Commission's Rules of Practice and Procedure (18 CFR §§ 385.211, 385.214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or to be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-5960 Filed 3-18-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP71-237-000; and CI71-714-000]

Panhandle Eastern Pipeline Co.; Pan Eastern Exploration Co.; Special Supply Refund Adjustment Report Filing

Issued: March 13, 1987.

Take notice that on February 2, 1987, Pan Eastern Exploration Company ("Pan East" or "Application"), filed with the Federal Energy Regulatory Commission (Commission) a Special Supply Refund Adjustment Report (Special Report) detailing the suspension of the Supply Refund Adjustments provisions effective December 31, 1986, pursuant to Article VI(B) of the Amended Stipulation and Agreement (Stipulation) filed in these proceedings on March 9, 1982. Under Article IV(B)(3) of the Stipulation, Supply Refund Adjustments provisions in contracts between Pan East and Panhandle Eastern Pipe Line Company (Panhandle) which provided a discount from the maximum lawful price were to be suspended and inoperative when the cumulative total of Supply Refund Adjustment dollars for volumes sold after January 1, 1973 exceeded the cumulative differential amount under Article III(A) of the Stipulation. The Special Report sets forth the current cumulative total of Supply Refund Adjustment dollars and the cumulative differential amount, together with a summary of the computation thereof.

Pan East asserts in the Special Report that it has more than satisfied its cumulative total Supply Refund Adjustments obligations and is suspending the Refund Adjustments. The suspension of the Refund Adjustments permits Pan East to collect the maximum lawful prices under its contracts with Panhandle without

discount and under the appropriate rates schedules and certificates, if applicable.

Contemporaneously with the filing of the Special Report, Pan East filed in these proceedings, pursuant to Article VIII of the Stipulation, a Final Status Report.¹ The Final Status Report details the amounts Pan East invested in gas lease acquisition, exploration, development, and production activities pursuant to Article III of the Stipulation. Under the Stipulation, upon acceptance by the Commission of the Final Status Report, the Stipulation will terminate as provided in Article VIII of the Stipulation.

Any person desiring to be heard or to protest Pan East's Special Report filing, should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's rules of practice and procedure.² All such motions or protests should be filed within 30 days from the issuance date of this Notice. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein or to participate as a party in any hearing herein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-5961 Filed 3-18-87; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 10100-000, et al.]

Hydroelectric Applications (Cascade River Hydro, et al.); Applications Filed With the Commission

Take notice that the following hydroelectric applications have been filed with the Federal Energy Regulatory Commission and are available for public inspection:

1. a. Type of Application: Preliminary Permit.
- b. Project No.: 10100-000.
- c. Date Filed: September 28, 1986.
- d. Applicant: Cascade River Hydro.
- e. Name of Project: Irene Creek.
- f. Location: On Irene Creek, tributary of the Cascade River, within the Snoqualmie-Mt. Baker National Forest, In Skagit County, Washington near the

¹ Notice of this filing was issued on March 4, 1987.

² 18 CFR 385.211 and 214 (1986).

town of Marblemount. T.35N., R.11E., sec. 13, S $\frac{1}{4}$; E $\frac{1}{2}$ NW $\frac{1}{4}$; W $\frac{1}{2}$ NE $\frac{1}{4}$; sec. 12, SW $\frac{1}{4}$; T.35N., R.12E., sec. 18, SW $\frac{1}{4}$ SW $\frac{1}{4}$; sec. 19, NW $\frac{1}{4}$.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)-825(r).

h. Contact Person:

Mr. Lawrence J. McMurtrey, President, Cascade River Hydro 12122-196th NE., Redmond, WA 98052 (206) 885-3986
Mr. Philip M. Botch, 8730 Overlake Drive W., Bellevue, WA 98004, (206) 455-1035

i. Comment Date: May 4, 1987.

j. Description of Project: The proposed project would consist of: (1) A 3-foot-high, 20-foot-long diversion dam at elevation 2,800 feet; (2) a 36-inch-diameter, 3,580-foot-long penstock; (3) a powerhouse containing a single generating unit with an installed capacity of 3,680 kW, producing approximately 16.11 GWh of energy annually; (4) a tailrace; (5) an access road; and (6) an 8-mile-long, 115-kV buried transmission line tying into a Puget Power and Light Company line. No new roads will be needed to carry out the studies under the preliminary permit. The Applicant estimates that the cost of conducting studies under the preliminary permit would be \$40,000.

k. Purpose of Project: Project power will be sold to Puget Power and Light Company.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

2 a. Type of Application: Preliminary Permit.

b. Project No.: 10101-000.

c. Date Filed: September 26, 1986.

d. Applicant: Cascade River Hydro.

e. Name of Project: Black Creek.

f. Location: On Black Creek, tributary of the Suiattle River, within Snoqualmie-Mt. Baker National Forest in Snohomish County, Washington, near the town of Darrington. T.32N., R.11E., sec. 17, SW $\frac{1}{4}$; sec. 20, SE $\frac{1}{4}$, S $\frac{1}{2}$ NW $\frac{1}{4}$, N $\frac{1}{2}$ SW $\frac{1}{4}$.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)-825(r).

h. Contact Person:

Mr. Lawrence J. McMurtrey, President, Cascade River Hydro, 12122-196th NE., Redmond, WA 98052

Mr. Philip M. Botch, 8730 Overlake Drive W., Bellevue, WA 98004, (206) 455-1035

i. Comment Date: May 4, 1987.

j. Description of Project: The proposed project would consist of: (1) A 3-foot-high, 15-foot-long diversion dam at elevation 2,200 feet; (2) a 30-inch-diameter, 6,975-foot-long penstock; (3) a powerhouse containing a single generating unit with an installed capacity of 1,230 kW, producing approximately 5.51 GWh of energy

annually; (4) a tailrace; (5) an 8-mile-long, 115-kV buried transmission line tying into an existing Puget Power and Light Company line. No new roads will be needed to conduct studies under the preliminary permit. The Applicant estimates that the cost of conducting studies under the preliminary permit would be \$40,000.

k. Purpose of Project: Project power would be sold to Puget Power and Light Company.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

3 a. Type of Application: Preliminary Permit.

b. Project No.: 10146-000.

c. Date Filed: October 30, 1986.

d. Applicant: Skykomish River Hydro.

e. Name of Project: San Juan Creek Project.

f. Location: In the Snoqualmie-Mt. Baker National Forest, on San Juan Creek, in Snohomish County, Washington. Township 28N and Range 11E.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)-825(r).

h. Contact Person: Mr. Lawrence J. McMurtrey, 12122-196th NE., Redmond, WA 98052, (206) 885-3986.

i. Comment Date: May 1, 1987.

j. Description of Project: The proposed project would consist of: (1) Two concrete diversion structures 18-inches wide with inlet elevations of 3,400 feet msl; (2) a bifurcated penstock 7,000 feet long and 18-inches in diameter leading to; (3) a powerplant at elevation 1,600 feet msl containing a single turbine/generator unit with a capacity of 2,240 kW operating at 1,800 feet of hydraulic head; and (4) a 12-mile-long, 115-kV transmission line. The applicant estimates the average annual energy production to the 9.4 GWh. The approximate cost of the studies under the permit would be \$40,000.

k. Purpose of Project: Applicant proposes to sell the power generated at the proposed facility.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

4 a. Type of Application: Preliminary Permit.

b. Project No: 10149-000.

c. Date Filed: October 30, 1986.

d. Applicant: Skykomish River Hydro.

e. Name of Project: Anderson Creek.

f. Location: On Anderson Creek, tributary of the Skykomish River within the Snoqualmie-Mt. Baker National Forest in Snohomish County, Washington near the town of Everett—

T. 29, N., R. 9 E.

Sec. 5, E $\frac{1}{2}$.

Sec. 8, NE $\frac{1}{4}$,
Sec. 9, NW $\frac{1}{4}$, W $\frac{1}{2}$ NE $\frac{1}{4}$.
T. 30 N., R. 9 E.
Sec. 20, E $\frac{1}{2}$ SW $\frac{1}{4}$.
Sec. 29, E $\frac{1}{2}$ W $\frac{1}{2}$.
Sec. 32, E $\frac{1}{2}$ W $\frac{1}{2}$.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)-825(r)

h. Contact Person: Mr. Lawrence J. McMurtrey, President, Skykomish River Hydro, 12122-196th NE., Redmond, WA 98052 (206) 885-3986.

i. Comment Date: May 1, 1987.

j. Description of Project: The proposed project would consist of: (1) Two 3-foot-high, 15-foot-long diversion dam at elevation 1,600 feet; (2) a pipeline; (3) an 18-inch-diameter, 6,000-foot-long penstock; (4) a powerhouse containing a single generating unit with an installed capacity of 1,400 kW, producing approximately 6.17 GWh of energy annually; (5) a tailrace; (6) a 1-mile-long transmission line tying into Puget Power and Light Company line. No new access road will be needed to conduct the studies. The Applicant estimates that the cost of the studies to be conducted under the preliminary permit would be \$40,000.

k. Purpose of Project: Project power would be sold to Puget Power and Light Company.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

5 a. Type of Application: Preliminary Permit.

b. Project No.: 10191-000.

c. Date Filed: November 24, 1986.

d. Applicant: Skykomish River Hydro.

e. Name of Project: Troublesome Creek.

f. Location: on Troublesome Creek within the Snoqualmie-Mt. Baker National Forest in T28N, R11E, near Skykomish in Snohomish County, Washington.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)-825(r).

h. Contact Person: Mr. Lawrence J. McMurtrey, 12122-196th NE., Redmond, WA 98052, (206) 885-3986.

i. Comment Date: May 1, 1987.

j. Description of Project: The proposed run-of-the-river project would consist of: (1) A 36-inch-wide intake structure buried in the stream at elevation 1,800 feet; (2) an 11,000-foot-long, 54-inch-diameter penstock; (3) a powerhouse containing one generating unit with a rated capacity of 3,700 kW; and (4) a 10-mile-long transmission line. Applicant estimates the average annual energy production to be 17.90 GWh. The applicant estimates that the cost of the work to be performed under the preliminary permit would be \$40,000.

k. Purpose of Project: The power produced is to be sold to the local power company.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

6 a. Type of Application: Preliminary Permit.

b. Project No.: 10193-000.

c. Date Filed: November 24, 1986.

d. Applicant: Sauk River Hydro.

e. Name of Project: Crystal Creek.

f. Location: On Crystal Creek within the Snoqualmie-Mt. Baker National Forest in T29N, R9E and T30N, R9E, near Darrington in Snohomish County, Washington.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)-825(r).

h. Contact Person: Mr. Lawrence J. McMurtrey, 12122-196th NE, Redmond, WA 98052, (206) 885-3986.

i. Comment Date: May 1, 1987.

j. Description of Project: The proposed run-of-the-river project would consist of: (1) A 3-foot-high concrete diversion structure at elevation 3,000 feet; (2) a 5,000-foot-long, 24-inch-diameter penstock; (3) a powerhouse containing one generating unit with a rated capacity of 2.88 MW; and (4) a 14-mile-long transmission line. Applicant estimates that the cost of the work to be performed under the preliminary permit would be \$40,000 and the average energy production would be 12.85 GWh.

k. Purpose of Project: The power produced is to be sold to the local power company.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

7 a. Type of Application: Preliminary Permit.

b. Project No.: 10194-000.

c. Date Filed: November 24, 1986.

d. Applicant: Sauk River Hydro.

e. Name of Project: Helena Creek.

f. Location: On Helena Creek within the Snoqualmie-Mt. Baker National Forest in T31N, R10E, near Darrington in Snohomish County, Washington.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)-825(r).

h. Contact Person: Mr. Lawrence J. McMurtrey, 12122-196th NE, Redmond, WA 98052, (206) 885-3986.

i. Comment Date: May 1, 1987.

j. Description of Project: The proposed run-of-the-river project would consist of (1) A 3-foot-high concrete diversion structure at elevation 2,400 feet; (2) a 15,742-foot-long, 24-inch-diameter penstock; (3) a powerhouse containing one generating unit with a rated capacity of 2,200 kW; and (4) an 8-mile-long transmission line. Applicant estimates the average annual energy production to be 14.90 GWh. The

applicant estimates the cost of the work to be performed under the preliminary permit would be \$40,000.

k. Purpose of Project: The power produced is to be sold to the local power company.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

8 a. Type of Application: Preliminary Permit.

b. Project No.: 10195-000.

c. Date Filed: November 24, 1986.

d. Applicant: Sauk River Hydro.

e. Name of Project: Goodman/Murphy.

f. Location: On Goodman and Murphy Creeks within the Snoqualmie-Mt. Baker National Forest in T31N, R10E, near Darrington in Snohomish County, Washington.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)-825(r).

h. Contact Person: Mr. Lawrence J. McMurtrey, 12122-196th NE, Redmond, WA 98052, (206) 885-3986.

i. Comment Date: May 1, 1987.

j. Description of Project: The proposed run-of-the-river project would consist of: (1) Two 3-foot-high concrete diversion structures at elevation 2,400 feet; (2) an 11,000-foot-long, 24-inch-diameter penstock; (3) a powerhouse containing one generating unit with a rated capacity of 3,680 kW; and (4) an 8-mile-long transmission line. Applicant estimates the average annual energy production to be 19.34 GWh. The Applicant estimates that the cost of the work to be performed under the preliminary permit would be \$40,000.

k. Purpose of Project: The power produced is to be sold to the local power company.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

9 a. Type of Application: Surrender of License.

b. Project No.: 2890-020.

c. Date Filed: February 5, 1987.

d. Applicant: Kings River Conservation District.

e. Name of Project: Dinkey Creek.

f. Location: On Dinkey Creek, Bear Creek, Laurel Creek, and Deer Creek, in Fresno County, California, within the Sierra National Forest.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)-825(r).

h. Contact Person:

Kings River Conservation District, 4886 E. Jensen Avenue, Fresno, CA 93725, (209) 237-5567;

Mr. Christopher D. Williams, McCarty, Noone & Williams, 490 L'Enfant Plaza East, Suite 3206, Washington, DC 20024, (202) 554-2955.

i. Comment Date: April 23, 1987.

j. Description of Proposed Action: On March 22, 1982, a license was issued to Kings River Conservation District to construct, operate, and maintain the Dinkey Creek Project No. 2890. The project would consist of 3 diversion weirs and tunnels, one each on Deer Creek, Bear Creek, and Laurel Creek, carrying flows to the Dinkey Creek Reservoir. On Dinkey Creek, the project would consist of a compacted rockfill dam, a reservoir, 2 penstocks, 2 powerhouses with a total capacity of 120 MW, a transmission line, access roads, and appurtenant facilities.

Licensee states that it has decided to surrender the license due to the termination of its power purchase contract with the Pacific Gas and Electric Company. No construction has begun on the project.

k. Anyone desiring to be heard or to make any protest about this action should file a motion to intervene or a protest with the Federal Energy Regulatory Commission in accordance with the requirements of the Commission's Rule of Practice and Procedure, 18 CFR 385.211 or 385.214 (1985). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in § 385.211 for protests. To become a party, or to participate in any hearing that might be held, a person must file a motion to intervene in accordance with the Commission's Rules. The Commission's address is: Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE, Washington, DC 20426.

10 a. Type of Application: Preliminary Permit.

b. Project No.: 10283-000.

c. Date Filed: January 29, 1987.

d. Applicant: Albert J. Gilewicz, P.E. and Bear Development Company, Inc.

e. Name of Project: Squaw Island/Black Rock Canal Hydropower.

f. Location: On Niagara River and Black Rock Canal, near City of Buffalo, in Erie County, New York.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)-825(r).

h. Contact Person: Mr. Albert J. Gilewicz, P.E., Consulting Engineer, 4600 Harlem Road, Amherst, NY 14226, (716) 839-3555.

i. Comment Date: April 23, 1987.

j. Competing Application: Project No. P-10267 Date Filed: January 27, 1987.

k. Description of Project: The proposed project will use water from the existing Black Rock Canal which is under the jurisdiction of the U.S. Army Corps of Engineers. The project would consist of: (1) A new 1,400-foot-long, 100-

foot-wide diversion canal from the Black Rock Canal to the Niagara River; (2) a new powerhouse containing 3 generating units with a total installed capacity of 2,250 kW at a design head of 6 feet; and (3) a 200-foot-long transmission line connecting to an existing Niagara Mohawk Corporation line.

The estimated average annual energy production is 10 million kWh. The project power would be sold to Niagara Mohawk Power Company. The applicant estimates that the cost of the work to be performed under the preliminary permit would be \$100,000.

1. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

11 a. Type of Application: Preliminary Permit.

b. Project No.: 10267-000.

c. Date Filed: January 27, 1987.

d. Applicant: The Clifton Corporation.

e. Name of Project: Black Rock Water Power.

f. Location: On Black Rock Canal, near City of Buffalo, in Erie County, New York.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791(a)-825(r).

h. Contact Person: Mr. Charles B. Mierek, The Clifton Corporation, Route 2, Box 302A, One Clifton—Glendale Road, Spartanburg, SC 29302, (803) 579-4405.

i. Comment Date: April 23, 1987.

j. Competing Application: Project No. P-10283 Date Filed: January 29, 1987.

k. Description of Project: The proposed project will use water from the existing Black Rock Canal which is under jurisdiction of the U.S. Army Corps of Engineers. The project would consist of: (1) A new 1,200-foot-long, 100-foot-wide diversion canal from just South of the existing Black Rock Lock to the Niagara River; (2) a new powerhouse containing 5 generating units with a total installed capacity of 1,000 kW at a design head of 6 feet; (3) a 200-foot-long tailrace discharging into the Niagara River; and (4) a 500-foot-long, 13.2-kV transmission line connecting to an existing Niagara Mohawk Corporation line.

The estimated average annual energy production is 7 million kWh. The project power would be sold to Niagara Mohawk Power Company. The applicant estimates that the cost of the work to be performed under the preliminary permit would be \$50,000.

1. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

12 a. Type of Application: Exemption (Less than 5 MW).

b. Project No.: 8679-001.

c. Date Filed: September 30, 1986.

d. Applicant: Sequoia Ranch.

e. Name of Project: Sequoia Ranch.

f. Location: On the Middle Fork of the Tule River in Tulare County, California.

g. Filed Pursuant to: Section 408 of the Energy Security Act of 1980 (16 U.S.C. 2705 and 2708 as amended).

h. Contact Person: Bruce W. Borrer, Sequoia Ranch, Route 2, Box 300, Springville, CA 93265, (209) 539-2351.

i. Comment Date: April 17, 1987.

j. Description of Project: The proposed run-of-river project would consist of: (1) An existing 13-foot-high and 110-foot-long concrete dam; (2) a small impoundment; (3) an existing intake structure at the south end of the dam; (4) an existing 762-foot-long power canal; (5) an existing culvert under Rio Vista Drive; (6) an existing 1,217-foot-long trapezoidal earth canal; (7) a new stilling basing; (8) a new 7,235-foot-long earth canal; (9) a new 425-foot-long, 42-inch-diameter steel penstock; (10) a new powerhouse with 3 turbine-generator units with a total installed capacity of 1,090 kW; (11) a new 60-foot-long transmission line; and (12) other appurtenances. Applicant estimates an average annual generation of 3,905,000 kWh. Project energy would be sold to the Southern California Edison Company.

k. This notice also consists of the following standard paragraphs: A3, A9, B, C, and D3b.

13 a. Type of Application: Exemption (5MW or less).

b. Project No.: 10082-000.

c. Date Filed: September 15, 1986.

d. Applicant: Incorporated Village of Hobart, New York.

e. Name of Project: Hobart Hydropower.

f. Location: On West Branch Delaware River, near town of Stamford, in Delaware County, New York.

g. Filed Pursuant to: Energy Security Act of 1980 Section 408 (16 U.S.C. 2705 and 2708).

h. Contact Person: Mr. Frederick Schoen, Mayor, Village of Hobart, Main Street, Hobart, NY 13788, (807) 538-9700.

i. Comment Date: April 17, 1987.

j. Description of Project: The proposed project would utilize two existing concrete gravity dams, known as the Hobart Upper and Lower Pond Dams owned by the Village of Hobart, an existing concrete penstock which runs along the stream channel from the Upper Pond Dam to just below the Lower Pond Dam and a new powerhouse. The project would consist of: (1) An existing 15.1-foot-high, 72-foot-long Upper Pond Dam creating a pond

with a surface area of 2.0 acres and a storage capacity of 15 acre-feet at surface elevation 1,623 feet; (2) an existing 17.3-foot-high, 82-foot-long Lower Pond Dam creating a pond with a surface area of 1.0 acre and a storage capacity of 7.4 acre-feet at surface elevation 1,614 feet; (3) an existing 1,090-foot-long, 48-inch-diameter concrete penstock from the Upper Pond Dam to 120 feet downstream of the Lower Pond Dam with minor modifications to inlet and outlet areas; (4) a new powerhouse containing a generating unit with a rated capacity of 55 kW at a design head of 18.5 feet and producing 200,000 kWh average annual energy; and (5) a 75-foot-long, 4.8-kV transmission line connecting to an existing utility line.

k. Purpose of Exemption: An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

1. This notice also consists of the following standard paragraphs: A3, A9, B, C, & D3a.

14 a. Type of Application: Preliminary Permit.

b. Project No.: 10159-000.

c. Date Filed: November 4, 1986.

d. Applicant: West Oregon Electric Cooperative, Inc.

e. Name of Project: Scoggins Hydroelectric Facility.

f. Location: On the Scoggins Creek near the town of Forest Grove, Washington County, Oregon.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791(a)-825(r).

h. Contact Person: George Smith, Manager, West Oregon Electric Cooperative, Inc., P.O. Box 69, Vernonia, OR 97064, (503) 429-3021.

i. Comment Date: April 17, 1987.

j. Competing Application: Project No. 10019-000, Date Filed: June 17, 1986.

k. Description of Project: The proposed project would utilize the Bureau of Reclamation's Scoggins Dam and Reservoir having a normal water surface elevation of 303.5 feet msl and would consist of: (1) A steel penstock approximately 200 feet long and 36 inches in diameter leading to: (2) a masonry powerhouse containing two turbine/generator units having a total installed capacity of 1,500 kW operating at 89 feet of hydraulic head; (3) a control house adjacent to the powerhouse containing the control, protective, and metering equipment; and (4) a 2.7-mile-long, 115-kV transmission line. The applicant estimates that the average annual energy generation would be 4,150

MWh. The approximate cost of the studies under the permit would be \$15,000.

I. Purpose of Project: The applicant intends to utilize the power generated at the proposed facilities for their own electrical power system.

m. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

Standard Paragraphs:

A3. Development Application

Any qualified development applicant desiring to file a competing application must submit to the Commission, on or before the specified comment date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified comment date for the particular application. Applications for preliminary permit will not be accepted in response to this notice.

A4. Development Application

Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, any competing development applications, must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

A5. Preliminary Permit

Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36 (1985)). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application.

A competing preliminary permit application must conform with 18 CFR 4.30(b) (1) and (9) and 4.36.

A7. Preliminary Permit

Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before the specified

comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application.

A competing license application must conform with 18 CFR 4.30(b) (1) and (9) and 4.36.

A8. Preliminary Permit

Public notice of the filing of the initial preliminary permit application, which has already been given, established the due date for filing competing preliminary permit and development applications or notices of intent. Any competing preliminary permit or development application, or notice of intent to file a competing preliminary permit or development application, must be filed in response to and in compliance with the public notice of the initial preliminary permit application. No competing applications or notices of intent to file competing applications may be filed in response to this notice.

A competing license application must conform with 18 CFR 4.30(b) (1) and (9) and 4.36.

A9. Notice of intent

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, include an unequivocal statement of intent to submit, if such an application may be filed, either (1) a preliminary permit application or (2) a development application (specify which type of application), and be served on the applicant(s) named in this public notice.

A10. Proposed Scope of Studies Under Permit

A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

B. Comments, Protests, or Motions to Intervene

Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of the

rules of practice and procedure, 18 CFR 385.210, 385.211, 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C. Filing and Service of Responsive Documents

Any filings must bear in all capital letters the title "COMMENTS", "RECOMMENDATIONS FOR TERMS AND CONDITIONS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST" or "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing is in response. Any of the above named documents must be filed by providing the original and the number of copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE, Washington, DC 20426. An additional copy must be sent to: Mr. Fred E. Springer, Director, Division of Project Management, Federal Energy Regulatory Commission, Room 203-RB, at the above address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D1. Agency Comments

States, agencies established pursuant to federal law that have the authority to prepare a comprehensive plan for improving, developing, and conserving a waterway affected by the project, federal and state agencies exercising administration over fish and wildlife, flood control, navigation, irrigation, recreation, cultural and other relevant resources of the state in which the project is located, and affected Indian tribes are requested to provide comments and recommendations for terms and conditions pursuant to the Federal Power Act as amended by the Electric Consumers Protection Act of 1988, the Fish and Wildlife Coordination Act, the Endangered Species Act, the National Historic Preservation Act, the Historical and Archeological Preservation Act, the National Environmental Policy Act, Pub. L. 88-29, and other applicable statutes.

Recommended terms and conditions must be based on supporting technical data filed with the Commission along with the recommendations, in order to comply with the requirement in section 313(b) of the Federal Power Act, 16 U.S.C. 825f(b), that Commission findings as to facts must be supported by substantial evidence.

All other federal, state, and local agencies that receive this notice through direct mailing from the Commission are requested to provide comments pursuant to the statutes listed above. No other formal requests will be made. Responses should be confined to substantive issues relevant to the issuance of a license. A copy of the application may be obtained directly from the applicant. If an agency does not respond to the Commission within the time set for filing, it will be presumed to have no comments. One copy of an agency's response must also be sent to the Applicant's representatives.

D2. Agency Comments

Federal, State, and local agencies are invited to file comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

D3a. Agency Comments

The U.S. Fish and Wildlife Service, the National Marine Fisheries Service, and the State Fish and Game agency(ies) are requested, for the purposes set forth in section 408 of the Energy Security Act of 1980, to file within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days

from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

D3b. Agency Comments

The U.S. Fish and Wildlife Service, the National Marine Fisheries Service, and the State Fish and Game agency(ies) are requested, for the purposes set forth in section 30 of the Federal Power Act, to file within 45 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State and local agencies are requested to provide comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 45 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Dated: March 16, 1987.

Kenneth F. Plumb,
Secretary.

[FR Doc. 87-5958 Filed 3-18-87; 8:45 am]
BILLING CODE 8717-01-M

[Docket Nos. C186-51-000, C186-51-001, C186-51-002, C187-348-000]

Application for Blanket Limited-Term Abandonment and Blanket Limited-Term Certificate of Public Convenience and Necessity With Pre-Granted Abandonments; Anadarko Petroleum Corp. et al.

March 13, 1987.

Take notice that on March 5, 1987, Anadarko Petroleum Corporation, Pan Eastern Exploration Company, Matagorda Island Development Corporation, Matagorda Island Exploration Corporation, and Pan Western Exploration Company (jointly referred to as "Applicants"), P.O. Box 1330, Houston, Texas 77251, filed an

Application pursuant to sections 4 and 7 of the Natural Gas Act ("NGA"), 15 U.S.C. 717c and 717f, and Parts 154 and 157 of the Federal Energy Regulatory Commission's ("Commission") Regulations, 18 CFR Parts 154 and 157, and 18 CFR 2.77 and 385.202 (1986) requesting (1) a blanket limited-term certificate of public convenience and necessity authorizing the sale for resale in interstate commerce of certain natural gas, with pre-granted abandonment and (2) a blanket limited-term abandonment, all for a term from April 1, 1987 through March 31, 1990, all as is more fully detailed in the Application which is on file with the Commission and open to public inspection.

Applicants state that the circumstances that led to the previous filing for such authorizations by its former parent company, Anadarko Production Company, granted by order of the Commission in Docket No. C186-51-000, dated December 5, 1985, as amended on March 31, 1986, will continue beyond the March 31, 1987, termination date set forth in the Commission's March 31, 1986, order in this proceeding. Further, Applicants state that the need for authority to market gas that might otherwise be shut-in or taken at substantially reduced levels as contemplated by the limited-term abandonment sought in the subject Application has proven beneficial to consumers, pipelines, and producers and is vital to providing Applicants an alternate gas marketing strategy.

Applicants stated that Anadarko Petroleum and Pan Eastern Exploration Company have, in the past, made sales under the authority of the limited-term abandonment granted to their former parent corporation, Anadarko Production Company, in Docket No. C186-51-000. Because the current authorization held by Anadarko Production Company will expire on March 31, 1987, the Applicants' ability to participate in the spot market beyond that date will cease absent Commission action on the subject Application prior to that date. As a result, Applicants requested expedited Commission review of their Application.

Specifically, Applicants request that the Commission authorize Applicants to:

- (i) Abandon for a three-year term sales for resale of gas subject to the Commission's jurisdiction under Section 1(b) of the NGA, 15 U.S.C. 717(b), and previously certificated by the Commission, to the extent that such gas is released by interstate pipelines for resale to third parties;
- (ii) Make sales for resale in interstate commerce for a period of three years,

without supply or market limitations, of the gas so abandoned, with pre-granted permanent abandonment authority for any such sales; and

(iii) Makes sales for resale in interstate commerce for a period of three years, without supply or market limitations, and with pre-granted permanent abandonment authority for any such sales, of gas that is owned by others having interests in the same wells as Applicants, to the extent that such co-owners agree to same.

Applicants also requested expedited approval of their Application and waiver of Parts 154 and 271 of the Commission's Regulations concerning the reporting requirements and maintenance of rate schedules for any sales made pursuant to this Application.

It appears reasonable and consistent with the public interest in these cases to prescribe a period shorter than normal for the filing of protests and petitions to intervene. Therefore, any person desiring to be heard to or to make any protest with reference to said application should on or before March 23, 1987, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or to be represented at the hearing.

Kenneth F. Plumb,
Secretary.

[FR Doc. 87-5958 Filed 3-18-87; 8:45 am]

BILLING CODE 6717-01-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC

20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224-011078.

Title: Los Angeles Terminal Agreement.

Parties:

The City of Los Angeles (Port)

Pasha Maritime Services, Inc. (Pasha)

Synopsis: The proposed agreement would give Pasha a preferential right to use the Port's Berths 174-181 as a bulk cargo/container terminal. The agreement would remain in effect for a period of 15 years.

By Order of the Federal Maritime Commission.

Dated: March 16, 1987.

Joseph C. Polking,
Secretary.

[FR Doc. 87-5924 Filed 3-18-87; 8:45 am]

BILLING CODE 6730-01-M

Filing and Effective Date of Agreement

The Federal Maritime Commission hereby gives notice, that on March 10, 1987, the following agreement was filed with the Commission pursuant to section 5, Shipping Act of 1984, and was deemed effective that date, to the extent it constitutes an assessment as described in paragraph (d) of section 5, Shipping Act of 1984.

Agreement No.: 201-011077.

Title: NYSA-ILA Assessment Agreement.

Parties:

New York Shipping Association

International Longshoremen's Association, AFL-CIO

Synopsis: The agreement replaces Agreement No. 201-000091 previously filed with the Commission. It contains essentially the same terms as the predecessor agreement except that it establishes reduced assessment rates for certain specified cargo.

Dated: March 16, 1987.

By Order of the Federal Maritime Commission.

Joseph C. Polking,
Secretary.

[FR Doc. 87-5925 Filed 3-18-87; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

First Union Corp. et al.; Formations of; Acquisition by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than April 9, 1987.

A. **Federal Reserve Bank of Richmond**
(Lloyd W. Bostian, Jr., Vice President)
701 East Byrd Street, Richmond, Virginia 23261:

1. *First Union Corporation*, Charlotte, North Carolina, and its subsidiary, First Union Corporation of Florida, Jacksonville, Florida; to acquire 100 percent of the voting shares of First Sarasota Bancorporation, Tampa, Florida, and thereby indirectly acquire City Commercial Bank, Sarasota, Florida.

B. **Federal Reserve Bank of St. Louis**
(Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Farmers Capital Bank Corporation*, Frankfort, Kentucky; to merge with General Bank Corporation of Kentucky, Horse Cave, Kentucky, and thereby indirectly acquire Horse Cave State Bank, Horse Cave, Kentucky.

C. **Federal Reserve Bank of Minneapolis** (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Rolla Holding Company, Inc.*, Rolla, North Dakota; to become a bank holding company by acquiring 100 percent of the voting shares of The First Bank of Rolla, Rolla, North Dakota.

D. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *First Caprock Bancshares, Inc.*, Claude, Texas; to become a bank holding company by acquiring 80 percent of the voting shares of The First National Bank of Claude, Claude, Texas.

Board of Governors of the Federal Reserve System, March 13, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-5891 Filed 3-18-87; 8:45 am]

BILLING CODE 6210-01-M

Carl Goetz; Acquisition of Shares of Banks or Bank Holding Companies

The notificant listed below has applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 3, 1987.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Carl Goetz*, Center, North Dakota; to acquire an additional 16.8 percent of the voting shares of Oliver Bancorporation, Inc., Center, North Dakota, and thereby indirectly acquire State Bank of Oliver County, Center, North Dakota.

Board of Governors of the Federal Reserve System, March 13, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-5892 Filed 3-18-87; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Statement of Organization, Functions, and Delegations of Authority

Part F. of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services, Health Care Financing Administration (HCFA), 49 FR 35247, dated September 6, 1984) is amended to include the Secretary's delegation of authority, to the Administrator, HCFA, to conduct demonstration projects regarding preventive health services under Medicare authorized under section 9314 of the Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. 99-272.

The specific changes to Part F. are described below:

Section F.30., Delegations of Authority, is amended by adding paragraphs W. and X. The new delegations of authority read as follows:

W. The authority under sections 9314 (a) and (c) of the Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. 99-272, to conduct 4-year demonstration projects in no fewer than five sites (at least one of which shall serve a rural area) designed to reduce disability and dependency through the provision of preventive health services to individuals entitled to benefits under Title XVIII of the Social Security Act, under the direction of accredited public or private nonprofit schools of public health or preventive medicine departments accredited by the Council on Education for Public Health.

X. The authority under section 9314(f) of the Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. 99-272, to determine the amounts to be paid (including the authority to determine the times and manner of payment) and to authorize payment out of the Federal Supplementary Medical Insurance Trust Fund, subject to the limitations of section 9314(f), of such amounts for grants and payments under contracts for the demonstration projects authorized by section 9314(a) of Pub. L. 99-272.

The authority herein delegated may be redelegated. This delegation of authority is effective immediately. In addition, I hereby affirm and ratify any actions taken by you which, in effect, involved the exercise of the subject authorities prior to the effective date of this delegation.

Dated: February 26, 1987.

Otis R. Bowen,

Secretary, Department of Health and Human Services.

[FR Doc. 87-5962 Filed 3-18-87; 8:45 am]

BILLING CODE 4120-03-M

Public Health Service

National Center for Health Services Research and Health Care Technology Assessment; Assessment of Medical Technology

The Public Health Service (PHS), through the Office of Health Technology Assessment (OHTA), announces that it is coordinating an assessment of what is known of the safety, clinical effectiveness, and indications for diagnostic tests for impotence and methods of treating impotence. For the purpose of this assessment, impotence is defined as a male's inability to accomplish sexual intercourse. Although psychogenic factors are responsible for up to one-half of the cases of impotence, organic reasons account for a large percentage of cases as well. PHS is soliciting information that would define the population of patients which might benefit from use of various tests (plethysmography, papaverine injections, nocturnal penile tumescence monitoring, in-house testing devices, etc.) to diagnose impotence. Information is also being sought to determine what population of patients might benefit from various treatment modalities (devices, surgical procedures or drugs). Information that would assist the PHS in developing guidelines for use in selecting patients for diagnostic testing, and identifying groups of patients who might benefit from specific therapeutic interventions is also being sought.

PHS assessments consist of a synthesis of information obtained from appropriate organizations in the private sector and from PHS and other agencies in the Federal Government. PHS assessments are based on the most current knowledge concerning the safety and clinical effectiveness of a technology. Based on this assessment, a PHS recommendation will be formulated to assist HCFA in establishing coverage policy for Medicare. The information being sought includes reviews and assessments of past, current, and planned research related to these technologies, bibliographies of published, controlled clinical trials and other well-designed clinical studies. Information related to the characterization of the patient population most likely to benefit from them, as well as on the clinical acceptability, effectiveness and extent of use of these technologies is also being sought. Any person or group wishing to provide OHTA with information relevant to this assessment should do so in writing no later than June 30, 1987 or

within 90 days from the date of publication of this notice.

Written material should be submitted to: Morgan N. Jackson, M.D., M.P.H., Office of Health Technology Assessment, NCHRS&HCTA, 5600 Fishers Lane Room 18A27, Rockville, MD 20857, (301) 443-4990.

Dated: March 10, 1987.

Enrique D. Carter,
Director, Office of Health Technology Assessment, National Center for Health Services Research and Health Care Technology Assessment.

[FR Doc. 87-5934 Filed 3-18-87; 8:45 am]

BILLING CODE 4160-17-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Intent To Prepare an Environmental Impact Statement; Contract and Lease Approvals; Tulalip Indian Reservation, Snohomish County, WA

AGENCY: Bureau of Indian Affairs, Department of the Interior.

ACTION: Notice of intent to prepare an environmental impact statement and notice of public scoping meeting.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs intends to gather information necessary for the preparation of an Environmental Impact Statement (EIS) for the Tulalip Tribe's proposal to construct and own a 3,000 ton per day solid waste resource recovery facility and a 480-MW electric power plant on the Tulalip Indian Reservation in Snohomish County, Washington, and for purposes of necessary Department of the Interior/Bureau of Indian Affairs approvals of contracts and leases related to such proposal. Public scoping meetings will be held to receive input and questions from members of the public regarding this proposal and preparation of this EIS. This notice is being furnished as required by the National Environmental Policy Act (NEPA) Regulations (40 CFR 1501.7) to obtain suggestions and information from other agencies and the public on the scope of issues to be addressed in the Environmental Impact Statement. Comments and participation in the scoping process are solicited.

DATES: Written comments should be received thirty (30) days from the date of this notice. Public scoping meetings will be held on Tuesday, April 7, 1987, at 1:30 p.m. and 7:30 p.m. in the Ginni Stevens Auditorium, Snohomish County Administration Building, 3000 Rockefeller Avenue, Everett, Washington 98201.

ADDRESS: Comments should be addressed to Mr. Stanley Speaks, Area Director, Portland Area Office, Bureau of Indian Affairs, P.O. Box 3785, Portland, Oregon 97208.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Taylor, Area Environmental Coordinator, Portland Area Office, Bureau of Indian Affairs, P.O. Box 3785, Portland, Oregon 97208; Telephone number (503) 231-2208 or FTS 429-2208.

SUPPLEMENTARY INFORMATION: The Bureau of Indian Affairs (BIA), Department of the Interior, will be requested to review and approve various tribal contracts and leases necessary for the construction, operation and ownership of the proposed 3,000 ton per day solid waste resource recovery facility and the 480-MW power plant on the Tulalip Indian Reservation, including: (1) Solid waste stream guarantee contracts with municipalities; (2) energy sales contract with a public utility; (3) design, construction, operation and maintenance contracts with the selected technology vendor; (4) waterline extension and water supply contract; (5) contracts with various consultants; and (6) lease approvals. Such approvals by the Bureau of Indian Affairs will be sought pursuant to 25 U.S.C. 81, 415. It is anticipated that the project will be financed through the issuance of tax exempt revenue bonds pursuant to the Indian Tribal Government Tax Status Act. The Bureau's approval of such bonds will also be sought under 25 U.S.C. 81, together with approval of necessary contracts with the selected bond underwriter and credit enhancer.

The proposed solid waste resource recovery facility will be located on an approximately 25 acre site in the northwestern quadrant of the Tulalip Indian Reservation, adjacent to the Interstate Highway 5 corridor. It will utilize mass burn technology for purposes of recovering energy from municipal solid waste. The Tribe is seeking solid waste stream guarantee contracts with Snohomish County, King County, and the City of Seattle. The Tribe has insisted that the best available technology be employed at such facility, and to that end, after careful review, has selected Ogden Martin Systems, Inc. to build and operate the facility because of their wide experience and exceptional achievement in high environmental standards on similar projects, including the new mass burn facility in Marion County, Oregon.

The facility will produce approximately 480 MWH per year of electricity, which will be sold pursuant

to contract to a regional public utility. The facility will have the capability of providing steam for development of planned, adjacent industrial and office facilities on tribal land. Ash residue will be disposed of in accordance with applicable laws at an approved landfill either upon the Tulalip Indian Reservation or at another approved landfill located elsewhere within the State of Washington. Two new Interstate Highway 5 interchanges are part of the Tribe's proposal.

It is anticipated that water will be supplied for the project pursuant to a water supply contract with the City of Everett. A water main will be extended from existing Everett transmission lines to a new reservoir to be located upon the Tulalip Indian Reservation.

To take advantage of the favorable marginal costs of oversizing, the waterline will be constructed with additional capacity so that it will have the capability of serving existing water needs upon the Tulalip Indian Reservation and within northern Snohomish County as well as future development that may occur. There are no specific development plans at this time.

The purpose and need for this action is that the Tribe would like to secure a long-term, stable source of revenue for purposes of operating its tribal government, and to increase and promote jobs and economic development within the Tulalip Indian Reservation. The project would also provide the most timely and least expensive solution to the emergent solid waste disposal problem in the Puget Sound Region, arising from rapidly diminishing landfill capacity and associated environmental concerns.

In addition, the project will add to long-term renewable energy supplies within the State of Washington.

The two principal alternatives identified are to build the project as planned or not to build the project. Impacts to be expected if the proposed action is implemented will be new air emissions from the plant and an increase in truck traffic associated with solid waste delivery and ash disposal.

The primary Federal permit anticipated for the project would be a Prevention of Significant Deterioration permit to be issued by Region 10 of the Environmental Protection Agency. Construction approval by the Federal Highway Administration for access development is also anticipated. Corps of Engineers section 10 and section 404 permits, as well as a variety of state and local permits, will be required for the planned water line extension.

The Tribe has requested that the Environmental Impact Statement, prepared for purposes of National Environmental Policy Act compliance, also be made sufficient for utilization by state and local agencies reviewing necessary water line permits under Washington's State Environmental Policy Act. It is the Bureau's intention to assume lead agency status and to comply with this request. Therefore, comments should be directed at both National Environmental Policy Act and State Environmental Policy Act compliance.

The environmental review of this project will be conducted in accordance with the requirements of the National Environmental Policy Act of 1969, as amended (43 U.S.C. 4371 et seq.); Council on Environmental Quality Regulations (40 CFR, Parts 1500 through 1508); Department of the Interior Procedures (516 DM 1-7), and the Bureau of Indian Affairs Handbook (30 BIAM Supplement 1).

We estimate the Draft Environmental Impact Statement will be made available to the public by late summer, 1987.

This notice is published in exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs, by 209 DM 8.

Dated: March 16, 1987.

Ross O. Swimmer,
Assistant Secretary, Indian Affairs.

[FR Doc. 87-5943 Filed 3-18-87; 8:45 am]
BILLING CODE 4310-02-M

Bureau of Land Management

[ID-060-07-4212-13; I-23203]

Coeur d'Alene District; Exchange of Public Lands; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action, exchange of public lands in Benewah and Kootenai Counties, Idaho.

SUMMARY: This Notice is to advise the public that the Emerald Empire Resource Area of the Bureau of Land Management (BLM) and Idaho Forest Industries, Inc. are proposing a land exchange. The following described public lands have been determined to be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of October 21, 1976, 43 U.S.C. 1716.

Boise Meridian, Idaho

T. 46 N., R. 1 W.,
Sec. 24 S½SE¼.
T. 49 N., R. 5 W.,

Sec. 3 SW¼;
Sec. 8 SE¼NE¼, N½SE¼;
Sec. 9 Lots 1 & 3;
Sec. 10 W½NE¼;
Sec. 17 NW¼SE¼.

Comprising 563.65 acres of public land. In exchange for these lands, the Federal Government will acquire the following described lands from Idaho Forest Industries, Inc.:

T. 48 N., R. 2 W.,
Sec. 19 Lots 2 & 3, N½NE¼, NE¼NW¼,
SE¼SW¼;
Sec. 20 W½SW¼;
Sec. 29 NW¼NW¼;
Sec. 30 NE¼NE¼.

T. 48 N., R. 3 W.,
Sec. 23 E½NE¼, NE¼SE¼;
Sec. 24 Lots 2, 3, 4, 5, NW¼SW¼.

Comprising 725.10 acres of private land. The purpose of this exchange is to improve the resource management programs of the Bureau of Land Management and the property management program of Idaho Forest Industries, Incorporated. The public lands to be exchanged are isolated parcels. The Idaho Forest Industries lands are intermingled with public and National Forest lands and have timber and wildlife habitat values that merit acquisition into public ownership. These lands will be managed for multiple use along with the adjoining public and National Forest lands. The exchange is consistent with the Bureau's land use plans.

Lands to be transferred from the United States will be subject to the following reservations:

1. A reservation of the United States of a right-of-way for ditches and canals constructed by authority of the United States under the Act of August 30, 1890 (43 U.S.C. 945).

2. Valid existing rights of record.

The public lands described in Kootenai County are presently under grazing lease to Forrest Godde, the holder of Grazing authorization 6002. The rights of Mr. Godde to graze domestic livestock on the lands described in grazing authorization 6002 that may transfer out of federal ownership shall cease upon title transfer because he has elected to waive these rights.

Lands to be acquired by the United States will be subject to valid existing rights of record.

The publication of this Notice in the *Federal Register* will segregate the public lands described above to the extent that they will not be subject to appropriation under the public land laws, including the mining laws. Any subsequently tendered application, allowance of which is discretionary, shall not be accepted, shall not be considered as filed, and shall be returned to the applicant. The segregative effect shall terminate as provided by 43 CFR 2201.1(b).

Comments

For a period of 45 days from the date of publication of this notice, interested parties may submit comments to the District Manager, Coeur d'Alene District Office, Bureau of Land Management, 1808 North Third Street, Coeur d'Alene,

Idaho 83814. Objections will be evaluated by the State Director who may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become the final determination of the Department of the Interior. Further information concerning the realty action can be obtained from Mert Lombard, Emerald Empire Area Manager, Coeur d'Alene District Office, (208) 765-7356.

Dated: March 9, 1987.

Fritz U. Rennebaum,
District Manager.

[FR Doc. 87-5893 Filed 3-18-87; 8:45 am]
BILLING CODE 4310-GG-M

[U-52894; UT-040-4212-14]

Realty Action Sale of Public Lands in Beaver County, UT

AGENCY: Bureau of Land Management, Interior.

ACTION: Under section 203 of the Federal Land Policy and Management Act of 1976 (43 USC 1716) public land described as Lot 2, Sec. 18, T. 29 S., R. 7 W., SLB&M, Utah, containing 40.30 acres, is proposed for sale by competitive sealed bidding at no less than the appraised fair market value of \$6,000.00. The lands described are hereby segregated from all forms of appropriation under the public land laws, including the mining laws, pending disposition of this action.

SUMMARY: The purpose of the sale is to dispose of public land that is difficult and uneconomical to manage by a government agency.

DATES: Comments should be submitted by May 16, 1987. The sale will be held on June 2, 1987, at 10:00 a.m.

ADDRESS: Detailed information concerning the sale, including bidding procedures, is available at the Beaver River Resource Area Office, 444 South Main, Cedar City, Utah 84720, (801) 586-2458. Comments should also be sent to the same address. The sale will be held in the Commission Chambers, Beaver County Courthouse, 105 East Center Street, Beaver, Utah.

SUPPLEMENTARY INFORMATION: The terms and conditions applicable to the sale are:

1. The sale will be for the surface estate only. Minerals will remain with the United States Government.
2. There is reserved to the United States, a right-of-way for ditches or canals constructed by the authority of the United States, Act of August 30, 1890, 26 Stat. 391, 43 U.S.C. 945.

3. Title transfer will be subject to valid existing rights including Right-of-Way U-44897 held by Utah Power and Light Company and Oil and Gas Lease U-52970.
4. If the public lands are not sold pursuant to this notice, they will remain available for sale on a continuing basis until sold or removed from the market. Sealed bids for subsequent sales may be submitted at any time; however, they must be submitted at the Beaver River Resource Area Office and will only be opened at 10:00 a.m. the first Tuesday of each month.

Any comments received during the comment period will be evaluated, and the District Manager may vacate or modify this realty action. In the absence of any objections, this realty action notice will be the final determination of the Department of the Interior.

Dated: March 10, 1987.

Morgan S. Jensen,
District Manager

[FR Doc. 87-5885 Filed 3-18-87; 8:45 am]

BILLING CODE 4310-DQ-M

[CO-942-06-4520-12]

Colorado; Filing of Plats of Survey

March 11, 1987.

The plats of survey of the following described land, will be officially filed in the Colorado State Office, Bureau of Land Management, Lakewood, Colorado, effective 10:00 a.m., March 11, 1987.

The plat, representing the dependent resurvey of a portion of the subdivisional lines and a portion of the center lines of section 24, T. 12 S., R. 70 W., Sixth Principal Meridian, Colorado, Group No. 824, was accepted March 5, 1987.

The plat, representing the dependent resurvey of a portion of the subdivisional lines, T. 5 N., R. 80 W., Sixth Principal Meridian, Colorado, Group No. 801, was accepted March 5, 1987.

The plat, representing the dependent resurvey of a portion of the subdivisional lines, T. 5 N., R. 82 W., Sixth Principal Meridian, Colorado, Group No. 801, was accepted March 3, 1987.

The plat, representing the dependent resurvey of a portion of the south boundary and the subdivisional lines, T. 6 N., R. 82 W., Sixth Principal Meridian, Colorado, Group No. 801, was accepted March 3, 1987.

The plat, representing the dependent resurvey of Tract No. 39 and a portion of Tract No. 42, T. 2 N., R. 86 W., Sixth

Principal Meridian, Colorado, Group No. 805, was accepted March 5, 1987.

The plat, representing the dependent resurvey of a portion of the Eleventh Guide Meridian West (west boundary, T. 10 N., R. 88 W.), east boundary, T. 10 N., R. 90 W., north boundary, the subdivisional lines, and Tract No. 37 and the survey of the subdivision of sections 5 and 6, T. 10 N., R. 89 W., Sixth Principal Meridian, Colorado, Group No. 781, was accepted March 3, 1987.

These surveys were executed to meet certain administrative needs of the U.S. Forest Service.

All inquiries about this land should be sent to the Colorado State Office, Bureau of Land Management, 2850 Youngfield Street, Lakewood, Colorado 80215.

Jack A. Eaves,
Chief, Cadastral Surveyor for Colorado.
[FR Doc. 87-5886 Filed 3-18-87; 8:45 am]

BILLING CODE 4310-JB-M

[NV-050-4322-14]

Las Vegas District Advisory Council Meeting

Notice is hereby given in accordance with Pub. L. 92-463 that a meeting of the Bureau of Land Management Las Vegas District Advisory Council will be held April 16, 1987.

The meeting will begin at 8:30 a.m. at the Saddle West Hotel, on highway 180, in Pahrump, Nevada.

The meeting agenda will include:

1. Election of officers.
 2. Update of Las Vegas District activities.
 3. Profile of Pahrump, Nevada.
 4. Kern River pipeline update.
 5. Red Rock Canyon exchange/sale update.
 6. The Nevada test site and its impact on the region.
 7. Update on the wild horse and burro program.
 8. Update on the Aero-Jet Exchange.
 9. Discussion of the BLM Christmas tree sales program.
 10. New business.
 11. Public comments.
 12. Field trip.
- The meeting of the Las Vegas District Advisory Council is open to the public. Persons wishing to make oral statements to the Council must notify the District Manager, Bureau of Land Management, Las Vegas District Office, 4765 West Vegas Drive, P.O. Box 26569, Las Vegas, Nevada, 89126, (702) 388-6403, by April 1, 1987.

Depending on the number of persons wishing to make oral statements, a per-person time limit may be established by the District Manager.

Summary minutes of the Las Vegas District Advisory Council Meeting will be maintained in the Bureau of Land Management Las Vegas District Office.

Charles Frost,

Acting District Manager.

[FR Doc. 87-5941 Filed 3-18-87; 8:45 am]

BILLING CODE 4310-HC-M

Minerals Management Service

Development Operations Coordination Document; Conoco Inc.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Conoco Inc. has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G1607, Block 55, portion, South Pass Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Venice, Louisiana.

DATE: The subject DOCD was deemed submitted on March 10, 1987.

ADDRESS: A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Michael J. Tolbert; Minerals Management Service, Gulf of Mexico OCS Region, Field Operations, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Telephone (504) 736-2867.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected local governments, and other interested parties become effective December 13, 1979 (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Dated: March 11, 1987.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 87-5887 Filed 3-18-87; 8:45 am]

BILLING CODE 4310-MR-M

Development Operations Coordination Document; Walter Oil and Gas Corp.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Walter Oil and Gas Corporation has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 4906, Block 56, Main Pass Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Venice, Louisiana.

DATE: The subject DOCD was deemed submitted on March 9, 1987. Comments must be received on or before April 3, 1987 or 15 days after the Coastal Management Section receives a copy of the plan from the Minerals Management Service.

ADDRESSES: A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday). A copy of the DOCD and the accompanying Consistency Certification are also available for public review at the Coastal Management Section Office located on the 10th Floor of the State Lands and Natural Resources Building, 625 North 4th Street, Baton Rouge, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday). The public may submit comments to the Coastal Management Section, Attention OCS Plans, Post Office Box 44487, Baton Rouge, Louisiana 70805.

FOR FURTHER INFORMATION CONTACT:

Ms. Angie D. Gobert; Minerals Management Service, Gulf of Mexico OCS Region, Field Operations, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Telephone (504) 736-2876.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is

considering approval of the DOCD and that it is available for public review. Additionally, this Notice is to inform the public, pursuant to § 930.61 of Title 15 of the CFR, that the Coastal Management Section/Louisiana Department of Natural Resources is reviewing the DOCD for consistency with the Louisiana Coastal Resources Program.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979 (44 FR 53685).

Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Dated: March 11, 1987.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 87-5888 Filed 3-18-87; 8:45 am]

BILLING CODE 4310-MR-M

Bureau of Reclamation

[Int-FES-79-55]

Final Environmental Impact Statement; Availability of Final Supplement; Municipal and Industrial System, Bonneville Unit, Central Utah Project, UT

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability of final supplement to the final environmental statement.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, as amended, the Department of the Interior has prepared a Final Supplement to the Final Environmental Statement (FES) on the Municipal and Industrial (M&I) System, originally filed with the Environmental Protection Agency in October 1979 (INT-FES 79-55).

FOR FURTHER INFORMATION: Copies of the final supplement are available for inspection at the following locations: Director, Office of Environmental Affairs, Room 7425, Bureau of Reclamation, Washington, DC 20240 (202) 343-4991

Division of Management Support, General Service, Library Section, Code 950, Engineering and Research Center, Denver Federal Center, Denver, Colorado 80225 (202) 234-3019
Regional Director, Bureau of

Reclamation, Upper Colorado Regional Office, P.O. Box 11568, Salt Lake City, Utah 84147 (801) 524-5580
Utah Projects Office, Bureau of Reclamation, 302 East 1860 South, P.O. Box 1338, Provo, Utah 84603 (801) 379-1000

Single copies of the statement may be obtained on request from the Director, Office of Environmental Affairs or the Regional Director at the above addresses. Copies also will be available for inspection in libraries in the project vicinity.

SUPPLEMENTARY INFORMATION: The M&I System will provide municipal and industrial and irrigation water for portions of central Utah. The system consists of the proposed Jordanelle Dam and Reservoir, to be located on the Provo River about 38 miles upstream from Utah Lake, and the Jordan and Alpine Aqueducts, which will convey M&I water to Utah and Salt Lake Counties. In addition, the system will provide municipal and industrial water to Wasatch County and supplemental irrigation water to the Heber-Francis area in Wasatch and Summit Counties. Operation of the project will also enhance water quality, stream fishery, and recreation values.

The supplement evaluates the environmental impacts of proposed modifications to the M&I System plan and impacts not covered by the FES. Such items include relocating U.S. Highway 189 along an alignment different from that described in the FES; adding a new Wasatch County road; relocating the outlet works of Jordanelle Dam from the right to the left abutment; adjusting the reservoir management boundary and land for project features; modifying the fishery mitigation/recreation plan between the proposed Jordanelle Reservoir and the existing Deer Creek Reservoir by refining Provo River access requirements and eliminating boating and tubing on the river; modifying the wildlife mitigation plan; evaluating impacts to area wetlands (not covered in the FES); and consultations with the Fish and Wildlife Service under section 7 of the Endangered Species Act for the June sucker, a recently listed endangered species.

Dated: March 13, 1987.

C. Dale Duval,

Commissioner.

[FR Doc. 87-5870 Filed 3-18-87; 8:45 am]

BILLING CODE 4310-09-M

INTERNATIONAL TRADE COMMISSION

[TA-503(a)-14 and 332-246]

Probable Economic Effect of Conversion of U.S. Generalized System of Preferences to the Nomenclature Structure of Proposed Harmonized System U.S. Tariff Schedule

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of hearing.

SUMMARY: Following receipt on March 9, 1987, of a request from the U.S. Trade Representative (USTR), made in part at the direction of the President, the Commission instituted investigation No. TA-503(a)-14 and 332-246 under sections 503(a) and 131(b) of the Trade Act of 1974 (19 U.S.C. 2463(a) and 2151(b)) and section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)) to provide advice on the probable economic effect of the conversion of the U.S. Generalized System of Preferences (GSP) to the new Harmonized System (HS) tariff nomenclature.

The United States and its major trading partners expect to implement the Harmonized Commodity Description and Coding System in their respective national tariffs on January 1, 1988. This will necessitate a recasting of the U.S. GSP into the nomenclature of the new Harmonized System United States Tariff Schedule, and a redesignation by the President of GSP eligible articles in the new tariff schedule as of January 1, 1988.

Pursuant to sections 503(a) and 131(a) of the Trade Act of 1974, and pursuant to the authority of the President delegated to the USTR by Executive Order 11846, the USTR requested the Commission to provide its advice, with respect to each article considered for GSP designation in the proposed new HS tariff schedule, as to the probable economic effect on United States industries producing like or directly competitive articles and on consumers of the application of a duty rate of free under the GSP. (It should be noted that the requested advice is for the effect of the conversion of the GSP to the HS tariff schedule and *not* for a reconsideration of the effect of GSP status for all prior GSP products.) The articles being proposed for GSP treatment under the HS nomenclature are contained in the proposed new HS tariff schedule. That document (known as the October 1986 Conversion of the TSUS into the Harmonized System, Revised) is available from the United

States International Trade Commission in Washington, DC and Commerce Department District Offices. USTR first announced the proposed conversion of the GSP program to the HS in the *Federal Register* of December 8, 1986 (51 FR 44163). In a subsequent *Federal Register* notice of March 6, 1987 (52 FR 7057), the USTR noted corrections to the above draft HS tariff schedule.

In addition, at the direction of the President, the Commission was requested pursuant to section 332(g) of the Tariff Act of 1930, and in accordance with section 504(c)(3)(A) of the Trade Act, to provide advice on whether any industry in the United States is likely to be adversely affected by the waiver of the application of section 504(c) of the Act with respect to imports of the articles listed by the USTR in the *Federal Register* of March 6, 1987 (52 FR 7057).

The Commission was asked to prepare its advice on the assumption that, based on imports in 1985, benefits of the GSP would not apply to imports from countries that would be excluded from receiving such benefits by virtue of the "competitive need" limits specified in section 504(c)(1) of the Act, except for imports from the specified beneficiary countries in the specified HS items (listed in 52 FR 7057) which would be waived from the application of section 504(c).

Section 504(d) of the Act exempts from the competitive need limits in section 504(c) articles for which no like or directly competitive article was being produced in the United States on January 3, 1985. Accordingly, pursuant to the authority of the President delegated to the USTR by Executive Order 11846, the Commission was requested to provide advice with respect to whether articles like or directly competitive with those designated as eligible for the GSP in the proposed HS tariff schedule were being produced in the United States on January 3, 1985.

EFFECTIVE DATE: March 13, 1987.

FOR FURTHER INFORMATION CONTACT:

- (1) Agricultural products, Mr. Lowell Grant (202-724-0099).
- (2) Chemical products, Mr. Ed Matusik (202-253-0492).
- (3) Textiles and apparel, Ms. Mary Sweet (202-523-0394).
- (4) Minerals and metals, Mr. Jim Lukes (202-523-0279).
- (5) Machinery and equipment, Ms. Sylvia McDonough (202-523-4587).
- (6) Miscellaneous manufactures, Mr. Carl Seastrum (202-724-1733).

All of the above are in the Commission's Office of Industries. For information on legal aspects of the

investigation contact Mr. William Gearhart of the Commission's Office of the General Counsel at 202-523-0487.

Public Hearing: A public hearing in connection with the investigation will be held in the Commission Hearing Room, 701 E Street NW., Washington, DC 20436, beginning at 9:30 a.m. on April 22, 1987, to be continued on April 23 and April 24, 1987 as required. All persons shall have the right to appear by counsel or in person, to present information, and to be heard. Persons wishing to appear at the public hearing should file requests to appear and should file prehearing briefs (original and 14 copies) with the Secretary, United States International Trade Commission, 701 E Street NW., Washington DC 20436, not later than noon, April 8, 1987.

Written submissions: In lieu of or in addition to appearances at the public hearing, interested persons are invited to submit written statements concerning the investigation. Written statements should be received by the close of business on April 22, 1987. Statements should provide a detailed description of the product or products of concern (including the proposed HS subheading and the current TSUS category) and detailed information on the impact of the change of particular concern. Commercial or financial information which a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. All submissions should be addressed to the Secretary at the Commission's Office in Washington, DC.

Hearing-impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 724-0002. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 523-0161.

Issued: March 13, 1987.

By order of the Commission.

Kenneth R. Mason,
Secretary.

[FR Doc. 87-5862 Filed 3-18-87; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. TA-406-11]

Ammonium Paratungstate and Tungstic Acid From the People's Republic of China; Import Investigation

AGENCY: United States International Trade Commission.

ACTION: Institution of an investigation under section 406(a) of the Trade Act of 1974 (19 U.S.C. 2436(a)) and scheduling of a public hearing in connection therewith.

SUMMARY: Following receipt on March 5, 1987, of a request from the United States Trade Representative, the United States International Trade Commission instituted investigation No. TA-406-11 under section 406(a) of the Trade Act of 1974 to determine, with respect to imports of ammonium paratungstate and tungstic acid from the People's Republic of China, provided for in items 471.40 and 416.40, respectively, of the Tariff Schedules of the United States, whether market disruption exists with respect to an article produced by a domestic industry. Section 406(e)(2) of the act defines such market disruption to exist whenever "imports of an article, like or directly competitive with an article produced by such domestic industry, are increasing rapidly, either absolutely or relatively, so as to be a significant cause of material injury, or threat thereof, to such domestic industry." The Commission will make its determination in this investigation by June 5, 1987.

EFFECTIVE DATE: March 5, 1987.

FOR FURTHER INFORMATION CONTACT:

Rebecca Woodings (202-523-0282), Office of Investigations, U.S. International Trade Commission, 701 E Street, NW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-724-0002. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-523-0161.

SUPPLEMENTARY INFORMATION:

Participation in the investigation.—Persons wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules (19 CFR 201.11), not later than twenty-one (21) days after publication of this notice in the *Federal Register*. Any entry of appearance filed after this date will be referred to the Chairman, who will determine whether to accept the late

entry for good cause shown by the person desiring to file the entry.

Service list.—Pursuant to § 201.11(d) of the Commission's rules (19 CFR 201.11(d)), the Secretary will prepare a service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance. In accordance with § 201.16(c) of the rules (19 CFR 201.16(c)), each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by the service list), and a certificate of service must accompany the document. The Secretary will not accept a document for filing without a certificate of service.

Hearing.—The Commission will hold a public hearing in connection with this investigation beginning at 9:30 a.m. on April 29, 1987, at the U.S. International Trade Commission Building, 701 E Street NW., Washington, DC. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission not later than the close of business (5:15 p.m.) on April 17, 1987. All persons desiring to appear at the hearing and make oral presentations, with the exception of public officials and persons not represented by counsel, should file prehearing briefs and attend a prehearing conference to be held at 9:30 a.m. on April 22, 1987, in room 117 of the U.S. International Trade Commission Building. The deadline for filing prehearing briefs is April 23, 1987. Posthearing briefs must be submitted not later than the close of business on May 5, 1987. Confidential material should be filed in accordance with the procedures described below.

Parties are encouraged to limit their testimony at the hearing to a nonconfidential summary and analysis of material contained in prehearing briefs and to information not available at the time the prehearing brief was submitted. Any written materials submitted at the hearing must be filed in accordance with the procedures described below and any confidential materials must be submitted at least three (3) working days prior to the hearing (see § 201.6(b)(2) of the Commission's rules (19 CFR 201.6(b)(2))).

Written submissions.—As stated above, parties to this investigation may file prehearing and posthearing briefs by the dates shown above. In addition, any person who has not entered an appearance as a party to the investigation may submit a written statement of information pertinent to the subject of the investigation on or before May 5, 1987. A signed original and fourteen (14) copies of each submission

must be filed with the Secretary to the Commission in accordance with § 201.8 of the Commission's rules (19 CFR 201.8). All written submissions except for confidential business data will be available for public inspection during regular business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary to the Commission.

Any business information for which confidential treatment is desired shall be submitted separately. The envelope and all pages of such submissions must be clearly labeled "Confidential Business Information." Confidential submissions and requests for confidential treatment must conform with the requirements of § 201.6 of the Commission's rules (19 CFR 201.6).

Remedy.—Parties are reminded that no separate hearing on the issue of remedy will be held. Those parties wishing to present arguments on the issue of remedy may do so orally at the hearing or in their prehearing or posthearing briefs or other written submissions.

For further information concerning the conduct of this investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, Part 206, Subparts A and C (19 CFR Part 206), and Part 201, Subparts A through E (19 CFR Part 201).

By order of the Commission.

Issued: March 13, 1987.

Kenneth R. Mason,
Secretary.

[FR Doc. 87-5861 Filed 3-18-87; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 337-TA-263]

Certain Office Filing Cabinets; Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on February 6, 1987, under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), on behalf of Supreme Equipment and Systems Corp., 170 53rd Street, Brooklyn, New York 11232. The complaint alleges unfair methods of competition and unfair acts in the importation into the United States of certain office filing cabinets, and in their sale, by reason of alleged direct infringement of at least claims 1-5 of U.S. Letters Patent 3,625,581. The

complaint further alleges that the effect or tendency of the unfair methods of competition and unfair acts is to destroy or substantially injure an industry, efficiently and economically operated, in the United States.

The complainant requests that the Commission institute an investigation and, after a full investigation, issue a permanent exclusion order and permanent cease and desist orders.

FOR FURTHER INFORMATION CONTACT: Regina A. Loughran, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202-523-1088.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930 and in § 210.12 of the Commission's Rules of Practice and Procedure (19 CFR 210.12).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on March 6, 1987, ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, an investigation be instituted to determine whether there is a violation of subsection (a) of section 337 in the unlawful importation into the United States of certain office filing cabinets, or in their sale, by reason of alleged direct infringement of claims 1-5 of U.S. Letters Patent 3,625,581, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complaint is: Supreme Equipment and Systems Corp., 170 53rd Street, Brooklyn, New York 11232.

(b) The respondents are the following companies, alleged to be in violation of section 337, and are the parties upon which the complaint is to be served: Desks, Inc., 1711 McGraw Avenue, Irvine, California 92714

Tukaway Computer Cabinets, Inc., 1711 McGraw Avenue, Irvine, California 92714

(c) Regina A. Loughran, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 701 E Street NW., Room 126, Washington, DC 20436, shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, Janet D. Saxon, Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding administrative law judge.

Responses must be submitted by the named respondents in accordance with § 210.21 of the Commission's Rules of Practice and Procedure (19 CFR 210.21). Pursuant to §§ 201.16(d) and 210.21(a) of the Rules (19 CFR 201.16(d) and 210.21(a)), such responses will be considered by the Commission if received not later than 20 days after the date of service of the complaint. Extensions of time for submitting a response will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings.

The complaint is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Room 156, Washington, DC 20436, telephone 202-523-0471. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-724-0002.

Issued: March 9, 1987.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 87-5864 Filed 3-18-87; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 337-TA-254]

Certain Small Aluminum Flashlights and Components Thereof; Partial Review and Modification of Initial Determination Adding Respondents and Declaring Investigation More Complicated

AGENCY: International Trade Commission.

ACTION: The Commission has determined in the above-captioned investigation not to review that portion of an initial determination (ID) to add two respondents to the investigation. The Commission has determined to review that portion of the ID declaring the investigation more complicated and

has further determined to modify that part by extending the deadline for completion of the investigation by 2 months, instead of 4 months.

FOR FURTHER INFORMATION CONTACT:

Jack Simmons, Esq., Office of the General Counsel, U.S. International Trade Commission, 701 E Street, NW., Washington, DC 20436, telephone 202-523-0493. Hearing impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202-724-0002.

SUPPLEMENTARY INFORMATION: On February 5, 1987, the Commission administrative law judge (ALJ) issued an ID (Order No. 7) that granted complainant's motion to join J.S. Corp., Seoul, Korea, and Precise Meters Co., Ltd., Taipei, Taiwan, as respondents in this investigation and that also granted complainant's motion to designate the investigation "more complicated," extending the deadline for completion of the investigation by 4 months. Two petitions for review of the ID were filed. No comments were received from other Government agencies.

The Commission has determined to review that part of the ID designating the investigation more complicated and extending the deadline by 4 months. The Commission has determined to modify that part of the ID by extending the deadline for completion of the investigation by 2 months, instead of 4 months. The extension of time is necessitated because of anticipated difficulties in obtaining information in view of the addition of the two new respondents and the present procedural schedule.

The authority for the Commission's action in this matter may be found in 19 U.S.C. 1137(b)(1) and 19 CFR 210.54, 210.56, and 210.59.

Copies of the Commission's action and order and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Washington, DC 20436, telephone 202-523-0161.

Issued: March 6, 1987.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 87-5867 Filed 3-18-87; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 731-TA-320 (Final)]

Certain Unfinished Mirrors From Belgium**Determination**

On the basis of the record¹ developed in the subject investigation, the Commission determines, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)), that an industry in the United States is not materially injured or threatened with material injury, and the establishment of an industry in the United States is not materially retarded, by reason of imports from Belgium of unfinished glass mirrors,² 15 square feet or larger in reflecting area, provided for in item 544.54 of the Tariff Schedules of the United States, that have been found by the Department of Commerce to be sold in the United States at less than fair value (LTFV).

Background

The Commission instituted this investigation effective September 12, 1986, following a preliminary determination by the Department of Commerce that imports of the above-referenced mirrors from Belgium were being sold at LTFV within the meaning of section 731 of the Act (19 U.S.C. 1673). Notice of the institution of the Commission's investigation and of a public hearing to be held in connection therewith was given by posting of the notice in the office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the *Federal Register* of October 1, 1986 (51 FR 35059). The hearing was held in Washington, DC, on December 2, 1986, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determination in this investigation to the Secretary of Commerce on March 11, 1987. The views of the Commission are contained in USITC Publication 1957 (March 1987), entitled "Certain Unfinished Mirrors From Belgium: Determination of the Commission in Investigation No. 731-TA-320 (Final) Under the Tariff Act of 1930. Together

With the Information Obtained in the Investigation."

Issued: March 11, 1987.
By order of the Commission.

Kenneth R. Mason,
Secretary.

[FR Doc. 87-5865 Filed 3-18-87; 8:45 am]
BILLING CODE 7020-02-M

[332-245]

Foreign Protection of Intellectual Property Rights and Effect on U.S. Industry and Trade

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation.

EFFECTIVE DATE: March 12, 1987.

FOR FURTHER INFORMATION CONTACT:

Mr. Mark D. Estes, General Manufactures Division, Office of Industries, U.S. International Trade Commission, Washington, DC 20436 (telephone 202-724-0977).

Background and Scope of Investigation: The Commission on March 12, 1987, instituted investigation No. 332-245, following receipt of a request on January 16, 1987, from the United States Trade Representative, at the direction of the President, that the Commission conduct an investigation under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)) concerning intellectual property rights issues and their effect on U.S. industry and international trade. The scheduled completion date for this study is September 21, 1987.

The Commission investigation will develop, to the extent possible, quantitative estimates of the distortions in U.S. trade associated with deficiencies in the protection provided by foreign countries to U.S. intellectual property rights, including trademarks, copyright, patents, semiconductor chip design, trade secrets, and other types of intellectual property rights. The study will attempt to measure the distortions in both U.S. merchandise transactions and selected service industries due to nonexistent, inadequate, discriminatory, and ineffectively enforced protection, as well as those due to foreign laws that conflict or are inconsistent with U.S. law. Specifically, the study will determine, as possible, the sales lost to counterfeit and other infringing products imported into the United States and U.S. export sales lost as a result of protection deficiencies, and evaluate which products, source countries, markets, and

protection deficiencies represent the most serious problems to U.S. firms. In addition the study will provide, as available, examples of U.S. employment losses resulting from foreign intellectual property right deficiencies, and measure the efforts made by U.S. firms to assert, protect, and enforce their intellectual property rights.

Public Hearing: The Commission will hold a public hearing on this investigation at the United States International Trade Commission Building, 701 E Street, NW., Washington, DC, beginning at 9:30 a.m. on April 21, 1987. All persons shall have the right to appear in person or be represented by counsel, to present information and to be heard. Persons wishing to appear at the public hearing should file requests to appear and should file prehearing briefs (original and 14 copies) with the Secretary, U.S. International Trade Commission, 701 E Street, NW., Washington, DC 20436, not later than noon, April 10, 1987. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 523-0161.

Written Submissions: Interested persons are invited to submit written statements concerning the investigation. Written statements should be received by the close of business on June 5, 1987. Commercial or financial information which a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. All submissions should be addressed to the Secretary, United States International Trade Commission, 701 E Street, NW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 724-0002.

Issued: March 12, 1987.
By order of the Commission.

Kenneth R. Mason,
Secretary.

[FR Doc. 87-5866 Filed 3-18-87; 8:45 am]
BILLING CODE 7020-02-M

¹ The record is defined in § 207.2(i) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(i)).

² Mirrors which have been subjected to any finishing operations such as beveling, etching, edging, or framing.

[Investigations Nos. 701-TA-275 Through 278 (Final), and 731-TA-327 Through 331 (Final)]

Certain Fresh Cut Flowers From Canada, Chile, Colombia, Costa Rica, Ecuador, Israel, and the Netherlands; Import Investigation

Determinations

On the basis of the record¹ developed in its countervailing duty investigation, the Commission has made its determinations pursuant to section 705(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)), as amended (the "Act"). In the tabulation of the Commission's determinations which follows, a determination of "affirmative" indicates that the Commission determines that an industry in the United States is materially injured by reason of imports of certain fresh cut flowers,² provided for in items 192.17 and 192.21 of the Tariff Schedules of the United States (TSUS),³ which have been found by the U.S. Department of Commerce to be subsidized by the governments of the cited countries:

Country, investigation No. and product	Determination
Canada, 701-TA-275 (Final):	
Standard carnations	Affirmative. ¹
Miniature carnations	Negative.
Chile, 701-TA-276 (Final):	Affirmative. ¹
Standard carnations	
Israel, 701-TA-277 (Final):	
Miniature carnations	Negative. ²
Gerberas	Negative.
The Netherlands, 701-TA-278 (Final):	
Miniature carnations	Negative.
Standard chrysanthemums	Affirmative. ¹
Alstroemeria	Negative.
Gerberas	Negative.

¹ Chairman Liebeler and Vice Chairman Brunsdale dissenting.

² Commissioners Eckes and Rohr find threat of material injury. They would not have found material injury by reason of the imports but for suspension of liquidation of entries of that merchandise.

On the basis of the record developed in its antidumping investigations, the

³ The record is defined in § 207.2(i) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(i)).

⁴ A determination of "negative" indicates that the Commission determines that an industry in the United States is not materially injured, nor threatened with material injury, nor is the establishment of an industry in the United States materially retarded, by reason of imports of certain fresh cut flowers.

⁵ Miniature carnations are provided for in item 192.17 of the Tariff Schedules of the United States (TSUS). All other fresh cut flowers subject to these investigations are provided for in item 192.21 of the TSUS.

Commission has made its determinations pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)). In the tabulation of the Commission's determinations which follows, a determination of "affirmative" indicates that the Commission determines that a industry in the United States is materially injured by reason of imports of certain fresh cut flowers, provided for in items 192.17 and 192.21 of the TSUS, which have been found by the U.S. Department of Commerce to be sold in the United States at less than fair value, except for the affirmative determination regarding miniature carnations from Colombia, where the Commission's affirmative determination is based on a threat of material injury to the domestic industry by reason of imports of miniature carnations, provided for in item 192.17 of the TSUS, which have been found by the U.S. Department of Commerce to be sold in the United States at less than fair value:

Country, investigation No. and product	Determination
Canada, 731-TA-327 (Final):	
Standard carnations	Affirmative. ¹
Miniature carnations	Negative.
Chile, 731-TA-328 (Final):	Affirmative. ¹
Standard carnations	
Colombia, 731-TA-329 (Final):	
Standard carnations	Affirmative. ¹
Miniature carnations	Affirmative. ¹
Standard chrysanthemums	Affirmative. ¹
Pompom chrysanthemums	Affirmative. ¹
Alstroemeria	Negative.
Gerberas	Negative.
Gypsophila	Negative.
Costa Rica, 731-TA-330 (Final):	
Standard carnations	Affirmative. ¹
Miniature carnations	Negative. ²
Pompom chrysanthemums	Affirmative. ¹
Ecuador, 731-TA-331 (Final):	
Standard carnations	Affirmative. ¹
Miniature carnations	Negative. ²
Standard chrysanthemums	Affirmative. ¹
Pompom chrysanthemums	Affirmative. ¹

¹ Chairman Liebeler and Vice Chairman Brunsdale dissenting.

² Commissioners Eckes and Rohr find threat of material injury. They would not have found material injury by reason of the imports but for suspension of liquidation of entries of that merchandise.

Background

On October 27, 1986, the U.S. Department of Commerce published its preliminary determinations that benefits which constitute subsidies, bounties, or

grants are being provided to producers or exporters of certain fresh cut flowers in Canada, Costa Rica, Ecuador, Colombia, Israel, the Netherlands, and Peru. On November 3, 1986, Commerce published its preliminary determinations that certain fresh cut flowers from Canada, Chile, Colombia, Costa Rica, Ecuador, Kenya, Mexico, and Peru are being, or are likely to be, sold in the United States at less than fair value. Accordingly, effective October 27, 1986, the U.S. International Trade Commission instituted final investigations under the applicable provisions of the Tariff Act of 1930 to determine whether an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry in the United States is materially retarded by reason of imports of the subject products into the United States. On February 3, 1987, Commerce published its final determination that benefits which constitute subsidies are being provided to producers or exporters of certain fresh cut flowers in Chile. Accordingly, effective February 3, 1987, the Commission instituted a corresponding final investigation.

Notice of the institution of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of notices in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing notices in the *Federal Register* on November 19, 1986 (51 FR 41840), January 7, 1987 (52 FR 610), and February 11, 1987 (52 FR 4391). The Commission's hearing was held in Washington, DC, on February 2, 1987, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on March 5, 1987. The views of the Commission are contained in USITC Publication 1956 (March 1987), entitled "Certain Fresh Cut Flowers From Canada, Chile, Colombia, Costa Rica, Ecuador, Israel, and the Netherlands: Determinations of the Commission in Investigations Nos. 701-TA-275 through 278 (Final) and 731-TA-327 through 331 (Final) Under the Tariff Act of 1930, Together With the Information Obtained in the Investigations."

Issued: March 5, 1987.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 87-5863 Filed 3-18-87; 8:45 am]

BILLING CODE 7020-02-M

**INTERSTATE COMMERCE
COMMISSION**

[Docket No. AB-18 (Sub-No. 93X)]

**Chesapeake and Ohio Railway Co.;
Exemption; Abandonment in Cass and
Miami Counties, IN**

AGENCY: Interstate Commerce
Commission.

ACTION: Notice of Exemption.

SUMMARY: The Interstate Commerce Commission exempts from the prior approval requirements of 49 U.S.C. 10903, *et seq.*, the abandonment by The Chesapeake and Ohio Railway Company of approximately 11.75 miles of track in Cass and Miami Counties, IN, subject to standard labor protective conditions.

DATES: This exemption will be effective on April 20, 1987. Petitions to stay must be filed by March 30, 1987. Petitions for reconsideration must be filed by April 8, 1987.

ADDRESSES: Send pleadings referring to Docket No. AB-18 (Sub-No. 93X) to:

- (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423
- (2) Petitioner's representative: Peter J. Schudtz, 100 North Charles Street, Baltimore, MD 21201

FOR FURTHER INFORMATION CONTACT:
Joseph H. Dettmar, (202) 275-7245.

SUPPLEMENTARY INFORMATION:

Additional information is contained in the Commission's decision. To purchase a copy of the full decision write to: T.S. InfoSystems, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423, or call 289-4357 (DC Metropolitan area) or toll free (800) 424-5403.

Decided: March 12, 1987.

By the Commission, Chairman Gradyson, Vice Chairman Lamboley, Commissioners Sterrett, Andre and Simmons.

Noreta R. McGee,

Secretary.

[FR Doc. 87-5931 Filed 3-18-87; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 30993]

**Boston and Maine Corp.; Lease and
Trackage Rights Exemption;
Springfield Terminal Railway Co.;
Exemption**

Boston and Maine Corporation (B&M) and Springfield Terminal Railway Company (ST) filed a notice of exemption for B&M to lease to ST the following lines of railroad in the vicinity of Nashua and Manchester, NH:

(a) The Northern Main Line between M.P. 34.50 (the Massachusetts-New Hampshire State line) and M.P. 56.00 (Manchester), a distance of approximately 21.50 miles;

(b) The Hillsboro Branch between the junction with the Northern Main Line at M.P. 38.96 (Nashua) and the end of track, a distance of approximately 34.97 miles;

(c) The north segment of the M&L Branch between the junction with the Northern Maine Line at M.P. 55.68 (Manchester) and the end of track in Derry; and

(d) The East Manchester Branch between the junction with the Northern Main Line at M.P. 55.68 (Manchester) and the end of track, a distance of approximately 2.01 miles.

In order to facilitate ST's operations and to permit ST to interchange traffic with B&M at Lowell, MA, B&M will assign to ST its right to move freight over the following lines of the Massachusetts Bay Transportation Authority (MBTA) in the vicinity North Chelmsford, MA:¹

(a) The Northern Main Line between M.P. 34.50 (the Massachusetts-New Hampshire State line) and M.P. 28.55 (North Chelmsford);

(b) The Freight Main Line between M.P. 28.55 (North Chelmsford) and M.P. 24.66 (Bleachery);

(c) The New Hampshire Route between M.P. 24.66 (Bleachery) and M.P. 23.00 (South of South Lowell); and

(d) The track known as the North leg of the wye at North Chelmsford connecting the Freight Main Line at Shay (M.P. 13.00 measured from Ayer Interlocking) and the Northern Main Line at North Chelmsford North (M.P. 28.91).

The purpose of these transactions is to enable ST to carry on operations now performed by B&M. B&M and ST are wholly owned subsidiaries of Guilford Transportation Industries, Inc. (GTI). GTI also owns the Maine Central

¹ B&M operates over these MBTA lines pursuant to an easement reserved in a deed of the rail property from the trustees of Boston and Maine Corporation, Debtor, to MBTA, approved in Finance Docket No. 26115, *B&M—Reorganization* [not printed], served May 7, 1976. B&M and ST contend that, the assignment of these easement rights does not require prior Commission approval under 49 U.S.C. 11343, because MBTA is not a carrier and the transaction, therefore, is not between two carriers. Section 11343(a)(6) requires prior Commission approval of an acquisition by a rail carrier, such as ST, of trackage rights to operate over a railroad line "owned or operated by another rail carrier." Since B&M is a rail carrier and operates over the MBTA lines, the assignment of its retained easement rights to ST is indistinguishable from a transfer of trackage rights between two carriers. Accordingly, prior Commission approval of the assignment of easement rights under section 11343 is necessary.

Railroad Company (MEC) and the Delaware and Hudson Railway Company (D&H). As a result of the proposed transactions, it is anticipated that ST will provide B&M's rail customers with more responsive and efficient service. B&M will improve its financial viability by eliminating costly operations relative to the revenues earned. With its lower cost structure, ST should be able to perform these operations on a more profitable basis.

Since B&M and ST are members of the same corporate family, both the lease and the assignment of trackage rights fall within the class of transactions that are exempt from the prior review requirements of 49 U.S.C. 11343. See 49 CFR 1180.2(d)(3). The transactions will not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with carriers outside the corporate family.²

Any employees affected by the lease transaction will be protected by the labor conditions set forth in *Mendocino Coast Ry., Inc.—Lease and Operate*, 354 I.C.C. 732 (1978), and 360 I.C.C. 653 (1980). Any employees affected by the trackage rights transaction will be protected by the conditions set forth in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast*, *supra*, 360 I.C.C. 653 (1980). These conditions satisfy the statutory requirements of 49 U.S.C. 10505(g)(2) for the respective transactions.³

Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of petitions to revoke will not stay the transactions.

Decided: March 12, 1987.

By the Commission, Jane F. Mackall,
Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 87-5920 Filed 3-18-87; 8:45 am]

BILLING CODE 7035-01-M

² The assignment of trackage rights also falls within another category of exempt transactions. See 49 CFR 1180.2(d)(7).

³ In three other notices of exemption proceedings: (Finance Docket No. 30965, involving a trackage rights and lease between D&H and ST; Finance Docket No. 30967, involving a lease between MEC and ST; and Finance Docket No. 30972, involving a lease between D&H and ST) the Railway Labor Executives' Association petitioned for the imposition of the labor protective conditions developed by the Commission in *New York Dock Ry.—Control—Brooklyn Eastern District*, 360 I.C.C. 60 (1979), in lieu of the *Mendocino* conditions. The Brotherhood of Locomotive Engineers has petitioned for similar relief in Finance Docket No. 30981, involving a lease between B&M and ST. A Commission decision will follow to consider these petitions.

[Docket No. AB-32 (Sub-No. 36X)]**Boston and Maine Corp. and Springfield Terminal Railway Co.; Abandonment and Discontinuance of Service; Exemption**

Boston and Maine Corporation (B&M) and Springfield Terminal Railway Company (ST) have filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments*. B&M will abandon a 14.75-mile portion of its line of railroad, known as the Canal Branch, between milepost 0.00 at New Haven and milepost 14.75 at Cheshire, in New Haven County, CT, and ST will discontinue service over this line segment.

Applicants have certified (1) that no local traffic has moved over the line for at least 2 years and that overhead traffic is not moved over the line or may be rerouted, and (2) that no formal complaint filed by a user of rail service on the line (or by a State or local governmental entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or any U.S. District Court, or has been decided in favor of the complainant within the 2-year period. The appropriate State agency has been notified in writing at least 10 days prior to the filing of this notice.

As a condition to use of this exemption, any employee affected by the abandonment or discontinuance shall be protected pursuant to *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

The exemption will be effective [30 days from service of this decision] (unless stayed pending reconsideration). Petitions to stay must be filed by [10 days after service], and petitions for reconsideration, including environmental, energy, and public use concerns, must be filed by 20 days after service with:

Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicants' representative:

Kristin Dorney, Iron Horse Park, North Billerica, MA 01862.

If the notice of exemption contains false or misleading information, use of the exemption is void *ab initio*.

A notice to the parties will be issued if environmental or public use conditions are imposed.

Decided: March 12, 1987.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.
Noreta R. McGee,
Secretary.

[FR Doc. 87-5921 Filed 3-18-87; 8:45 am]
BILLING CODE 7035-01-M

[Docket No. AB-6 (Sub-No. 283X)]**Burlington, Northern Railroad Co.; Abandonment Exemption; in Cherokee County, KS**

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Interstate Commerce Commission exempts from the prior approval requirements of 49 U.S.C. 10903, *et seq.*, the abandonment by the Burlington Northern Railroad Company of a 7.20-mile line of railroad between Galena Jct. (M.P. 340.80) and Baxter Springs (M.P. 348.00) in Cherokee County, KS, subject to standard employee protective conditions.

DATES: This exemption is effective on April 20, 1987. Petitions to stay must be filed by April 3, 1987 and petitions for reconsideration must be filed by April 13, 1987.

ADDRESSES: Send pleadings referring to Docket No. AB-6 (Sub-No. 283X) to:

- (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423
- (2) Petitioner's representative: Peter M. Lee, 3800 Continental Plaza, 777 Main Street, Fort Worth, TX 76102

FOR FURTHER INFORMATION CONTACT:
Joseph H. Dettmar, (202) 275-7245.

SUPPLEMENTARY INFORMATION:

Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to T.S. InfoSystems, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423, or call 289-4357 (DD Metropolitan area) or toll free (800) 424-5403.

Decided: March 3, 1987.

By the Commission, Chairman Gradyson, Vice Chairman Lambole, Commissioners Sterrett, Andre, and Simmons. Vice Chairman Lambole and Commissioner Simmons dissented with separate expressions.

Noreta R. McGee,

Secretary.

[FR Doc. 87-5922 Filed 3-18-87; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-55 (Sub-No. 198X)]**CSX Transportation, Inc.; Abandonment Exemption in Harlan County, KY**

CSX Transportation, Inc. (CSX) has filed a notice of exemption under 49 CFR Part 1152 Subpart F—*Exempt Abandonments* to abandon its 4.34-mile line of railroad known as the Banner Fork Branch between milepost WV-232.35 and WV-236.69 in Harlan County, KY.

Applicant has certified (1) that no local traffic has moved over the line for at least 2 years and that overhead traffic is not moved over the line, and (2) that no formal complaint filed by a user of rail service on the line (or by a State or local governmental entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or any U.S. District Court or has been decided in favor of the complainant within the 2-year period. The appropriate State agency has been notified in writing at least 10 days prior to the filing of this notice.

As a condition to use of this exemption, any employee affected by the abandonment shall be protected pursuant to *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979).

This exemption will be effective April 20, 1987, (unless stayed pending reconsideration). Petitions to stay must be filed by March 30, 1987, and petitions for reconsideration including environmental, energy, and public use concerns, must be filed by April 8, 1987, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representative: Peter J. Shudtz, 100 North Charles Street, Baltimore, MD 21201.

If the notice of exemption contains false or misleading information, use of the exemption is void *ab initio*.

A notice to the parties will be issued if use of the exemption is conditioned upon environmental or public use conditions.

Dated: March 12, 1987.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 87-5923 Filed 3-18-87; 8:45 am]

BILLING CODE 7035-01-M

[No. MC-F-18128]

Puget Sound Freight Lines, Inc.; Control Exemption; NPE, Inc.

AGENCY: Interstate Commerce Commission.

ACTION: Notice of proposed exemption.

SUMMARY: Puget Sound Freight Lines, Inc. (Puget), a noncarrier, has filed a petition under 49 U.S.C. 11343(e). Puget seeks an exemption from the requirement of prior regulatory approval for its acquisition of control of motor carrier NPE, Inc. (NPE) (MC-166669), through purchase of all of the latter's stock.

Puget now controls motor carriers Puget Sound Truck Lines, Inc. (MC-85255), and Truck Load Express, Inc. (MC-170165), and water carrier Puget Sound Freight Lines (W-505). NPE is currently a wholly-owned subsidiary of Silver Eagle Industries, which also owns motor carrier Silver Eagle Company (MC-32779). Acquisition of control of a carrier by a person that is not a carrier but that controls any number of carriers may be carried out only under Commission regulation or under an exemption from regulation. See 49 U.S.C. 11343(a)(5) and 11343(e).

Petitioner states that the acquisition of NPE will promote competitive and efficient transportation within the territory involved. Also, Puget asserts that it will be able to provide additional services to its shippers. Finally, petitioner argues that the transaction is limited in scope because NPE operates fewer than 30 pieces of equipment.

DATE: Comments must be received by April 20, 1987.

ADDRESSES: Send comments (an original and 10 copies) referring to Docket No. MC-F-18128 to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423
and

(2) Petitioners' representative: James F. Walker, Puget Sound Freight Lines, P.O. Box 24526, Seattle, WA 98124

FOR FURTHER INFORMATION CONTACT: Jasneeth C. Metz, (202) 275-7974.

SUPPLEMENTARY INFORMATION:

Petitioners seek an exemption under 49 U.S.C. 11343(e) and the Commission's regulations in *Procedures—Handling Exemptions Filed by Motor Carriers*, 367 I.C.C. 113 (1982).

A copy of the petition may be obtained from petitioners' representative, or it may be inspected at the Washington, DC office of the Interstate Commerce Commission during normal business hours.

Decided: March 11, 1987.

By the Commission, Chairman Gradison, Vice Chairman Lamboley, Commissioners Sterrett, Andre, and Simmons.

Noreta R. McGee,
Secretary.

[FR Doc. 87-5919 Filed 3-18-87; 8:45 am]

BILLING CODE 7035-01-M

Andre concurred in the holding of the decision.

Noreta R. McGee,
Secretary.

[FR Doc. 87-5918 Filed 3-18-87; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Information Collection(s) Under Review

March 16, 1987

The Office of Management and Budget (OMB) has been sent for review the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35) since the last list was published. Entries are grouped into submission categories. Each entry contains the following information: (1) The name and telephone number of the Agency Clearance Office (from whom a copy of the form/supporting documents is available); (2) the office of the agency issuing the form; (3) the title of the form; (4) the agency form number, if applicable; (5) how often the form must be filled out; (6) who will be required or asked to report; an estimate of the number of responses; (7) an estimate of the total number of respondents; (8) an estimate of the total number of hours needed to fill out the form; (9) an indication of whether section 3504(h) of Pub. L. 96-511 applies; and, (10) the name and the telephone number of the person or office responsible for the OMB review. Copies of the proposed form(s) and the supporting documentation may be obtained from the Agency Clearance Officer whose name and telephone number appear under the agency name. Comments and questions regarding the item(s) contained in this list should be directed to the reviewer listed at the end of each entry and to the Agency Clearance Officer. If you anticipate commenting on a form but find that time to prepare will prevent you from submitting comments promptly, you should advise the reviewer and the Agency Clearance Officer of your intent as early as possible.

Department of Justice Agency Clearance Officer: Larry E. Miesse, 202/633-4312.

New Collection(s)

(1) Larry E. Miesse, 202/633-4312

(2) National Institute of Corrections, Department of Justice

(3) Jail Classification System Development Study

(4) No form number

(5) One-time

FOR FURTHER INFORMATION CONTACT:

Paul Markoff, (202) 275-7960.

or

Andrew L. Lyon, (202) 275-7291

SUPPLEMENTARY INFORMATION:

Additional information is contained in the Commission's full decision. A copy may be purchased from T.S. InfoSystems, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423, or call toll-free (800) 424-5403, or (202) 289-4357 in the Washington, DC, metropolitan area.

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Authority: 49 U.S.C. 11701, 10706, and 10321; sec. 7(c)(2), Pub. L. 99-521, 100 Stat. 2995 (49 U.S.C. 10706(d)(1)(E)).

Decided: March 11, 1987.

By the Commission, Chairman Gradison, Vice Chairman Lamboley, Commissioners Sterrett, Andre, and Simmons. Commissioner

- (6) State and local governments. Study is to collect information regarding jail classification systems from volunteer respondents to develop a model objective jail classification system.
 (7) 150 respondents
 (8) 300 burden hours
 (9) Not applicable under 3504(h)
 (10) Jeff Hill—395-7340

New Collection(s)

- (1) Larry E. Miesse, 202/633-4312
 (2) Immigration and Naturalization Service, Department of Justice
 (3) Employment Eligibility Verification
 (4) I-9
 (5) One time
 (6) Individuals or households, businesses or other for-profit, small businesses or organizations. Used to facilitate compliance with section 101 of the Immigration Reform and Control Act of 1986.
 (7) 135,000,000 respondents; 30,000 recordkeepers
 (8) 24,900,000 burden hours
 (9) Not applicable under 3504(h)
 (10) Jeff Hill—395-7340

Larry E. Miesse,
Clearance Officer, Department of Justice.
 [FR Doc. 87-5869 Filed 3-18-87; 8:45 am]

BILLING CODE 4410-10-M

Antitrust Division**National Cooperative Research Notifications; Industry University Center for Glass Research**

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, Pub. L. 98-462 (the "Act"), written notice has been filed by the Industry-University Center for Glass Research at the New York State College of Ceramics, Alfred University, Alfred, New York (the "Center"). The additional written notification was filed simultaneously with the Attorney General and the Federal Trade Commission on February 20, 1987, disclosing changes in the membership of the Center.

The additional written notification was filed for the purpose of extending the protection of section 4 of the Act limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. The notification identifying the original parties to the project, and the nature and objectives of that project, is published at 51 FR 32262 (September 10, 1986).

Effective December 8, 1986, U.S. Borax Research became a member of the Center, and on January 22, 1987, CertainTeed Corp. also became a member of the Center. Owens-Corning

Fiberglass Corporation is no longer a member of the Center.

Joseph H. Widmar,
Director of Operations, Antitrust Division.
 [FR Doc. 87-5898 Filed 3-18-87; 8:45 am]
 BILLING CODE 4410-01-M

National Cooperative Research Notifications; Microelectronics and Computer Technology Corp.

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, Pub. L. 98-462 (the "Act"), Microelectronics and Computer Technology Corporation ("MCC") has filed an additional written notification simultaneously with the Attorney General and the Federal Trade Commission on February 25, 1987 disclosing changes in the membership of MCC. The additional written notification was filed for the purpose of extending the protections of section 4 of the Act limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. The notification identifying the original parties to the project, and the nature and objectives of that project, is published at 50 FR 2633 (January 17, 1985).

Effective January 1, 1987, Gould Inc. and each of its subsidiaries, and CTU of Delaware, Inc., each of its subsidiaries and each entity deemed its subsidiary for the purposes of participation in MCC, were no longer parties to MCC.

Joseph H. Widmar,
Director of Operations, Antitrust Division.
 [FR Doc. 87-5899 Filed 3-8-87; 8:45 am]
 BILLING CODE 4410-01-M

Bureau of Justice Assistance**Narcotics Control Discretionary Grant Program; Announcement**

AGENCY: Bureau of Justice Assistance; Justice.

ACTION: Final notice.

SUMMARY: The Bureau of Justice Assistance is publishing the program announcement for the Narcotics Control Discretionary Grant Program of the "Anti-Drug Abuse Act of 1986" [Subtitle K—State and Local Law Enforcement Assistance] and is requesting proposals for announced programs.

EFFECTIVE DATE: March 19, 1987.

FOR FURTHER INFORMATION CONTACT: For general information about the priorities and range of discretionary programs contact James C. Swain, Director Discretionary Grant Programs Division, 633 Indiana Avenue, NW., Washington, DC 20531. For specific

information on program requirements contact the person indicated in the text for each program.

ADDRESS: All final applications and concept papers (original plus two copies) should be addressed to the Bureau of Justice Assistance, 633 Indiana Avenue, NW., Washington, DC 20531. A copy of the concept paper should also be sent to the State Office which administers the Narcotics Control Program in the state(s) affected by the proposed program.

SUPPLEMENTARY INFORMATION: The "Anti-Drug Abuse Act of 1986" which established the State and Local Assistance for Narcotics Control Program was signed into law on October 27, 1986. Section 1311 of the Act sets aside 20 percent of the total amount appropriated for the Program in a special discretionary fund for use by the Director in carrying out the purposes established in Section 1302 of the Act. Those purposes can be summarized as follows:

- Providing more widespread apprehension of persons who violate state and local laws relating to the production, possession and transfer of controlled substances;
- Providing more widespread prosecution of persons accused of violating such state and local laws;
- Providing more widespread adjudication of cases involving persons accused of violating such state and local laws;
- Providing additional public correctional resources for the detention of persons convicted of violating state and local laws relating to the production, possession or transfer of controlled substances and establishing and improving treatment and rehabilitative counseling provided to drug dependent persons convicted of violating state and local laws;
- Conducting programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted;
- Providing programs which identify and meet the needs of drug-dependent offenders;
- Conducting demonstration programs, in conjunction with local law enforcement officials, in areas in which there is a high incidence of drug abuse and drug trafficking to expedite the prosecution of major drug offenders by identifying major drug offenders and moving these offenders expeditiously through the judicial system.

The Bureau of Justice Assistance solicited recommendations from several thousand Federal, state and local law enforcement, prosecution, judicial, corrections and treatment practitioners to assist with the development of the priorities for the discretionary grant program. Working groups of practitioners and national experts were established to review the recommendations received, to identify effective programs which are responsive to those recommendations and to recommend funding priorities in each of the program areas.

The resulting program priorities reflect a strategy which is designed to assist and enhance state and local drug control efforts by:

- Developing drug data sources, disseminating drug data and developing techniques for analyzing drug data for the purpose of defining the problem and assessing the impact and effectiveness of drug control efforts;
- Extending and disseminating programs of proven effectiveness to areas of need;
- Developing and testing the effectiveness of new programs and practices;
- Developing programs which focus on key areas of criminal justice dilemma and discretion; and
- Providing training and technical assistance to assist with the implementation of effective programs and practices.

The strategy for the discretionary programs is to provide direct, and progressively more complete, information and guidance for the states in their development and implementation of statewide strategies for the conduct of the block grant program. The discretionary program is designed to enhance the capacity of each state to define the drug problem and to focus program development on areas of greatest need.

The program strategy also reflects cognizance of: the specific mandate of The Bureau of Justice Assistance and its relationship to the mandates of the Departments of Education and Health and Human Services, thus the programs are limited to criminal justice and to certain key areas of linkage with other social service systems; the anticipated short term nature of Federal funding, thus programs selected are those which will provide the most direct and lasting impact; and the need to put the money to work in the most immediate, responsible manner, thus program selection has been influenced by the availability of strong interest and

expertise in the field. The timetables set out below in each Program Description are established so as to permit our obligation of these funds by the end of this Fiscal Year.

Application and Award Process: This program announcement contains proposal requests for the major portion of the approximately \$44 million available. The Bureau of Justice Assistance has made every effort to establish an open and competitive application process. Applications or concept papers are being requested from government agencies as well as public and private nonprofit organizations. A panel of experts will be established in each of the program areas to review those applications submitted on a competitive basis. Some awards will be negotiated directly with organizations which are uniquely qualified to provide specific services. Such awards are described in this announcement.

All applications will be reviewed to insure that they are cost effective, in addition to meeting the requirements outlined in the program description. All applications will be required to take special cognizance of the victims of drug-related crime, most notably the victims of domestic violence. Geographic distribution of projects will be considered for all programs which result in grants for implementation in several sites.

Description of Discretionary Programs: The following is a description of the programs included in this announcement and the due dates for concept papers and applications.

Authority: 1302 (1).

Program Title: Crack/Focused Substance Enforcement Program.

Background: This program is a hybrid enforcement approach incorporating elements successfully utilized in DEA State and Local Task Forces, Organized Crime/Narcotics Program (OCN) Task Forces and the old LEAA Organized Crime Discretionary Grant Program to focus on the enforcement and reduced availability of crack in major urban areas. The Task Force approach to drug enforcement is universally recognized by enforcement and prosecutorial officials as a viable method for dealing with drug activities and can be readily adopted to a specific drug enforcement.

Goal Objective: The goal of the CTF Program is to improve the capabilities of State and Local law enforcement agencies to investigate and immobilize crack cocaine trafficking organizations.

A. Enhance the ability of law enforcement agencies to attack higher-level crack cocaine trafficking organizations significant to their areas.

B. Increase the rates of arrests, prosecution, conviction, drug removals, and asset forfeitures related to crack traffickers and/or organizations.

C. Reduce the incidence of armed robberies and property related crimes committed to support crack cocaine habits.

D. Reduce the incidence of violent crime (i.e., homicides) related to crack cocaine distribution.

E. Improve the ability of state and local officers to develop strong Federal prosecution against crack traffickers by utilizing the current Federal statutes.

F. Increase the utilization of CCE and RICO statutes to target and immobilize crack trafficking organizations with evidence normally considered inflammatory (i.e., homicides) introduced in court through the RICO statute.

G. Facilitate the development, implementation and dissemination of intelligence information on crack trafficking organizations by all members involved in the CTFs.

Program Description: This particular effort will significantly enhance state, local and Federal efforts to combat the rapidly growing availability of crack and the threat it poses to our nation's youth. This enhancement reflects the basis of our overall enforcement strategy of integrated operations and makes available the resources to establish viable crack task forces in metropolitan areas where they presently do not exist. The program includes the participations of the U.S. Attorneys and the Drug Enforcement Administration. Federal Agency participation in each project is a program requirement. Grant funds will be used primarily for confidential expenditures (PE/PI), overtime, specialized equipment if necessary, and some administrative costs. DEA will pledge personnel and technical assistance support to each of these efforts. An effort will be made to assess the impact of such task forces on the pretrial service, prosecution, defense, adjudication, and corrections operations of selected metropolitan sites through before and after assessments of transaction statistics on movement of cases and people.

Grant Period: Up to five sites will be selected competitively by BJA based on internately developed criteria. The project duration will be 15 months to include 3 months start-up and 12 months of operation.

Award Amounts: Up to five individual projects will be funded at approximately \$300,000 each for a program total of \$1,500,000.

Eligibility Criteria: Applicants are confined to Urban Law Enforcement Agencies. Each should submit a concept paper of no more than ten pages (including a one page budget summary) which addresses the following criteria:

- Data collection and analysis for identifying the problem and allocating available resources;
- Emphasis on early involvement of the prosecution and court functions in order to ensure that both citizen rights and system impact issues are addressed;
- Vigorous enforcement effort to arrest and convict crack dealers;
- Undercover buy program concerned with enforcement efforts aimed at the street retailer who has become the most observable manifestation of crack cocaine traffic;
- Investigations are to be aimed at highest level of traffic to pursue CCE and RICO prosecutions;
- Asset seizure and forfeiture efforts when practical;
- Coordination of project mission with cognizant forensic laboratory services;
- Formal participation of DEA, U.S. Attorney and other Federal agencies as appropriate;
- Operational guidelines will be formulated and agreed upon by all participating agencies in task force;

Selection will in part be dependent on the level, commitment, and effective utilization of an organization's own resources in the development and implementation of the project.

References: N/A.

Due Dates: Concept papers must be postmarked no later than May 1, 1987.

Contact Person: The BJA contact for additional information on this program is Richard Ward, Chief, Law Enforcement Branch, 202/272-5974.

Authority: 1302 (1).

Project Title: Street Sales Enforcement Program.

Background: In theory, street-level drug enforcement is one of the most effective uses of local police resources to combat drugs and the problem they create. In practice, it is not always so. For every innovative program that has succeeded, an almost identical program has been much less successful. This suggests that jurisdictions should design and implement their own program tailored to their own local conditions, and relying on the full range of local law enforcement, municipal, and community resources available. Collection and analysis of drug market and abuse data is important. Without them, the police run the risk of concentrating on less important markets or individuals, or of

displacing the problem to different times, places, and distribution networks. The lack of good information also makes it difficult to redirect efforts once they have begun.

Goal/Objective: To demonstrate effective police efforts to target street level narcotic dealers and buyers through effective planning, investigation, and prosecution.

Program Description: This demonstration program will be offered for the purpose of strengthening urban enforcement and prosecution efforts targeted on street narcotics dealers and buyers.

Five to six projects will be funded to plan for and implement or strengthen existing large city narcotic investigation and prosecution efforts targeted at street level narcotic dealers and buyers.

At minimum, the demonstration sites should address the following elements:

- Data collection and analysis for identifying and using available resources and for using results of internal evaluation to revise programs to fit changing conditions;
- Emphasis on early involvement of the prosecution and court functions in order to ensure that both citizen rights and system impact issues are addressed;
- Train and utilize uniform personnel and certify uniformed officers as narcotics experts for testifying in court;
- Deployment of street teams for ongoing investigations and arrests of street narcotic dealers and buyers, and for being responsive to citizen complaints regarding narcotic conditions;
- Vigorous enforcement effort to arrest and convict narcotic addicts;
- Organization and deployment of mobile task forces to target those areas of the city where street sales of drugs have become blatant. The ideology behind the task force concept is that of vigorous enforcement accompanied by aggressive prosecution and public knowledge;
- Undercover buy program concerned with enforcement efforts aimed at the street retailer who has become the most observable manifestation of narcotic traffic;
- Asset seizure and forfeiture efforts when practical; and
- Coordination of project mission with cognizant forensic laboratory services.

The Bureau of Justice Assistance will arrange with the National Institute of Justice for the design and management of an evaluation of this program.

Grant Period: Projects will be funded for 18 months with the expectation that

they will go through a 3 month organization and planning phase, and a 15 month implementation phase.

Award Amounts: Five to six projects will be awarded in the range of \$300,000 to \$400,000 each for a program total of \$2,000,000.

Eligibility Criteria: Applicants, limited to urban law enforcement jurisdictions, should submit a concept paper of approximately 10 pages, plus a one-page summary budget.

The concept paper should provide summary descriptions of how the project will be developed and administered, including the elements listed in the Program Description Section.

Selection will in part be dependent on the level, commitment, and effective utilization of an organization's own resources in the development and implementation of the project.

References: N/A.

Due Dates: Concept papers of approximately 10 pages (plus one page budget summary) must be postmarked no later than April 30, 1987.

Contact Person: The BJA contact for additional information on this program is Richard Ward, Chief, Law Enforcement Branch, 202/724-5974.

Authority: 1302(1).

Program Title: Technical Assistance and Training for State and Local Narcotics Control Assistance Program.

Background: Through the provisions of Title 1 of the Anti-Drug Abuse Act of 1986, which addresses Drug Enforcement, Congress has clearly intended the Bureau of Justice Assistance to fund programs that will have a profound and immediate effect on illicit drug trafficking in the United States. The Block Grants for Drug Enforcement Programs will provide funds to the States to support each State's statewide strategy for enforcement of State and local laws relating to the production, possession, and transfer or sale of controlled substances. To ensure that the enforcement Block Grants have every means of successful implementation, technical assistance and training support will be provided to the State and local law enforcement agencies. This assistance will also be extended as appropriate to the law enforcement/prosecution Discretionary Grants funded by the BJA. Although this technical assistance and training effort will, by its nature, have a wide range of topic areas, driven by the States' strategies, it is envisioned that specific efforts will focus on the management and use of confidential funds, asset seizure and forfeiture, illicit drug interdiction efforts, officer safety,

apprehension methods, and the preparation of civil and criminal cases to ensure successful prosecutions.

Goal/Objective: The goal of this effort is the provision of technical assistance and training in law enforcement/prosecution programs undertaken by the States and BJA Discretionary Grantees.

Program Description: This program is designed to provide technical assistance, to conduct training, and to perform related tasks in support of the BJA Block and Discretionary grant programs.

The following tasks have been identified:

- Design and produce a plan for the orderly conduct of the direction and coordination of TA and training purposes and tasks based on the States' strategies as submitted and accepted by BJA and BJA law enforcement/prosecution Discretionary Grant efforts.
- Transmit information and procedures/instructions about the TA/training purposes and tasks to BJA staff, Discretionary Grantees, and others as required.
- Identify, document, update, and report on law enforcement/prosecution subgrants awarded by the States through the Block Grants for Drug Law Enforcement Programs.
- Design, compose, produce, and transmit, on a regular basis, a formal publication (Network Reporter) for the national network of subgrantees and Discretionary Grantees to inform agencies about illicit drug enforcement efforts.
- Design, conduct, and report on an assessment of TA/training needs identified for subgrantees and Discretionary Grantees.
- Design, conduct, support, monitor, and report on a national narcotic enforcement training program for subgrantees and Discretionary Grantees based on the above assessment.
- Design, conduct, support, monitor, and report on a national narcotic enforcement technical assistance resource team program and identify, coordinate, and support key consultants to serve as a program development advisory group.
- Research, compose, produce, and transmit selected manuals, handbooks, monographs, and catalogs for use by others.

Grant period: The duration period for the cooperative agreement will be 18 months.

Award Amount: One cooperative agreement will be made for \$1,500,000.

Eligibility Criteria: Private non-profit organizations are requested to submit

proposals based on the tasks articulated in the Program Description. Award recommendations will be made based on the quality of task performance plans, the expertise of applicant staff, and the proposed use of funds.

References: N/A.

Due Date: Applications must be postmarked no later than April 15, 1987.

Program contact: The Bureau of Justice Assistance contact for additional information on this program is Richard Ward, Chief, Law Enforcement Branch, 202/724-5974.

Authority: 1302(2).

Program Title: Asset Seizure and Forfeiture Program.

Background: This program is based on previous research and development funded by the National Institute of Justice and others dealing with asset removal and forfeiture as an effective means of depriving illicit drug traffickers of economic support and incentive. National Institute of Justice research also points to effective application of forfeiture laws and rules as a means of converting illicit capital to law enforcement purposes and generating major financial benefits to the community. Research has been and is currently being conducted on methods to be used to enhance the productivity of law enforcement narcotics control and asset seizure and forfeiture. It is recognized that, in the field of narcotics enforcement, asset seizure and forfeiture statutes are the weapons that enable police officials to present a balanced attack against illicit drug dealers. However, experience has shown that passage of such legislation does not, by itself, guarantee a successful asset seizure program. Full exploitation of new Federal and state laws depends on adequate training and technical assistance in the field.

Goal/Objective: The BJA Seizure and Forfeiture Program is designed to provide operational training and technical assistance to local law enforcement and prosecution personnel to familiarize them with the pertinent local, state and Federal laws and protocols, the conduct of financial investigations, coordination activities with the prosecutor and other agencies having jurisdiction in financial matters, and to alleviate difficulties encountered before, during, and after asset seizure.

Program Description: BJA has an existing grant with the Police Executive Research Forum (PERF) to further research this issue, develop a training methodology that is practical and useful to state and local law enforcement agencies in the conduct of investigations involving civil and criminal forfeitures, and to deliver that training to law

enforcement personnel in four states. A supplemental grant will be made to PERF to train law enforcement personnel and prosecutors in 12 to 14 additional states during an 18-month duration period of the grant. BJA will retain a strong management interest during the development and throughout the life of the program.

In addition, a model local program will be developed consistent with the training design and 4 sites will be selected for demonstration programs during the second phase of the project.

Grant Period: The grant period will be 18 months.

Award Amount: One supplemental award of approximately \$1,650,000 will be made.

Eligibility Criteria: The current cooperative agreement with the Police Executive Research Forum (PERF) will be supplemented to both expand the training program and develop the local model programs.

References: N/A.

Due Date: N/A.

Program Contact: The BJA contact for additional information on this program is Richard Ward, Chief, Law Enforcement Branch, 202/724-5974.

Authority: 1302 (1).

Program Title: BJA/FBI Financial Investigations Training.

Background: This program was developed as a result of a mutual interest in the area of financial investigations training as a primary weapon in the fight against narcotics trafficking on the part of both BJA and the FBI and the expressed interest of a number of law enforcement professional organizations in upgrading their constituents capabilities in this area. The tremendous amount of interest expressed in this area resulted in a decision on the part of BJA to focus on financial investigations as a key part of the overall enforcement strategy.

Goal/Objective: This program will provide for the development and institutionalization of a financial investigations training course for state and local investigators at the FBI Training Center in Quantico, Va.

Program Description: This program will be designed to offer three primary components: (1) Comprehensive training in specific financial investigative techniques for state and local investigators, (2) a program designed to train trainers, and (3) the development of a computer classroom for long term training in financial investigations and analysis. This latter component will feature the development of a curriculum and the delivery of training in computer based investigations. On a long term

basis, the bulk of the training will occur at the FBI Training Center in Quantico, Va. Some of the first year training will occur at selected state and local sites.

The Bureau of Justice Assistance will enter into an inter-agency agreement with the Federal Bureau of Investigation to develop and implement this training program.

Grant Period: This project will be funded for a three year period.

Award Amount: The inter-agency agreement will be for \$2,500,000.

Eligibility Criteria: N/A.

References: N/A.

Due Dates: N/A.

Contact Person: The BJA contact for additional information on this program is Richard Ward, Chief, Law Enforcement Branch, 202/724-5974.

Authority: 1302 (1).

Program Title: Problem-Oriented Approach to Drug Enforcement.

Background: Problem-oriented policing is the outgrowth of 20 years of research into police operations that converge on three main themes: Increased effectiveness by attaching underlying problems that give rise to incidents that consume patrol and detective time; reliance on the expertise and creativity of line officers, as well as other agency support systems, to study problems carefully and develop innovative solutions; and closer involvement with the various communities within a jurisdiction to make sure the police are addressing the needs of citizens.

Goal/Objective: To create a controlled substance abuse assessment mechanism that incorporates the views of line officers, department support groups, and citizens for guiding policy and resource allocation to effect a coordinated response to the illicit drug problem by law enforcement officials, medical facilities, local schools, drug treatment facilities, and other community organizations.

Program Description: The purpose of this program is to help police and their communities deal more effectively with illicit drug trafficking and use. Although progress has been made in some areas, the search for solutions remains foremost on the agendas of criminal justice administrators, educators, parents, and the community at large. Success in addressing this problem has been limited due to five complex factors that are present to some degree in every community:

- The diversity of the controlled substances (both legal and illegal) abused and the changing patterns of abuse.

- The dynamic nature of communities in general, their changing population

patterns, social interactions, and changing values.

- The inadequacy of information and data measuring techniques to evaluate the extent and scope of the overall problem and underlying causes of the problem.
- The lack of comprehensive strategies to combat the problem.
- The lack of full coordination of the resources employed to control the problem.

Up to four law enforcement sites will be funded to develop reliance on the expertise and creativity of line officers and support personnel to study the drug enforcement problems carefully and develop innovative responses for arrest of drug traffickers and users, seizure of illicit drugs and offender assets, and successful prosecutions.

Grant Period: One cooperative agreement will be awarded to the Police Executive Research Forum (PERF) to assist BJA with site selection and to provide assistance to the sites for a period of 18 months.

Award Amounts: The cooperative agreement will be awarded in the amount of \$1,200,000.

Eligibility Criteria: Four sites will be recommended by PERF and selected by BJA according to their ability:

- To develop a community/police organizational structure for implementing the program.
- To generate a community-based data collections system for selected controlled substance abuse indicators.
- To implement a method for correlation and analysis of controlled substance abuse data with census track demographic data.
- To utilize a method which will yield information from line officers and department support services together with data from the community that will allow for problem assessment and a coordinated response to the problem.
- To develop a weighting system to establish and demonstrate the relationship between controlled substance and serious criminal activity.

References: N/A.

Due Dates: Since these funds will be contracted by PERF to BJA selected sites, no due dates are being announced.

Contact Person: The BJA contact for additional information on this program is Richard H. Ward, Chief, Law Enforcement Branch (202) 724-5974.

Authority: 1302 (1).

Program Title: Pharmaceutical Diversion Program.

Background: The diversion of pharmaceuticals into the illicit market

and resultant abuse of these controlled substances remains a major drug abuse and drug law enforcement problem, accounting for 54% of the Drug Abuse Warning Network (DAWN) mentions in 1985. These diverted drugs become available to the drug abuser as a result of illegal activity by registrants, prescription fraud and abuse, indiscriminate prescribing, and theft. Despite admirable efforts, investigation of diversion by persons licensed by states has been generally inadequate because of insufficient resources.

Goal/Objective: The goal of this program is to strengthen the role of law enforcement, professional licensing boards and regulatory agencies in reducing diversion of legitimately produced controlled substances.

Program Description: This program will be designed to provide for the development of an overall diversion controlled strategy that includes the following components: (1) The establishment of a system or enhancement of an existing system for collecting and analyzing data on the diversion of controlled substances; (2) the conduct of investigations of diversions and the provision of professional license discipline; (3) the improvement of regulatory controls against diversion; (4) the prevention and detection of forged, altered, or illegal prescriptions and the identification of practitioners who prescribe excessively; and (5) the training of law enforcement, prosecutorial, and regulatory personnel to improve the control of diversion. A key component of this program will be the establishment of a formalized coordination mechanism involving regulatory agencies, law enforcement, and professional licensing boards. In addition, a portion of these funds will be set aside for the Department to conduct an analysis of pharmaceutical problems and related operational and training needs.

Grant Period: The grant period for projects funded under this program will be 15 months with a three month development phase and a one year implementation phase.

Award Amounts: Up to five sites will be awarded approximately \$300,000 each for a program total of \$1,500,000.

Eligibility Criteria: Applicants who are limited to state or local law enforcement jurisdictions should submit a concept paper of approximately 10 pages including a one page budget summary.

The concept paper must provide a summary description of how the project will be developed and administered, and must address the following elements:

- A description of the role of each participating agency (must include law enforcement, regulatory, and licensing authorities),
- A description of the project organizational structure,
- A description of the nature and extent of the problem,
- A formal coordination with DEA and other appropriate Federal agencies,
- Methodology for collecting and analyzing diversion data,
- A description of how regulatory controls will be improved,
- Methods for detecting forged, altered, or illegal prescriptions,
- A description of investigatory procedures to be utilized, and,
- A description of anticipated training needs and how those needs will be met.

Selection will in part be dependent on the level, commitment, and effective utilization of an organization's own resources in the development and implementation of the project.

References: N/A.

Due Dates: Concepts papers must be postmarked no later than May 1, 1987.

Contact Person: The BJA contact person for additional information on this program is Richard Ward, Chief, Law Enforcement Branch, 202/724-5974.

Authority: 1302 (1).

Program Title: BJS Justice Drug Data Clearinghouse.

Background: Numerous requests received by the Bureau of Justice Statistics (BJS) and by the BJA have underscored the need of the justice system for credible, accessible and directly useful data on drugs and the justice system, including the drug-crime relationship and the implications, for criminal justice policy and programs, of the infusion of a growing number of drug-dependent offenders. While data are gathered by a number of agencies, they are seldom consolidated and made available in a form directly useful to justice agencies. In essence, we risk commencing this major Federal drug effort without a clear baseline from which to assess its impact. This effort is designed as a direct remedy to each of these problems.

Goal/Objective: This program will provide direct assistance to local, state and Federal anti-drug efforts, through the identification, collection and analysis of drug-crime information necessary for strategic and tactical planning.

Program Description: Through an Interagency Agreement from BJA, working in concert with the Departments of Health and Human Services and Education, and drawing

upon the expertise of national organizations, the Bureau of Justice Statistics will proceed immediately to oversee the steps necessary to: Develop a pointer system which will identify existing sources for drug information in the justice system; collect drug information relevant to justice, which is not now being collected; analyze and present drug information in a form directly useful to justice policy makers and practitioners; assess the quality of drug information available to the justice system. This effort will take the form of a clearinghouse which will: provide an "800" number for direct access; gather and analyze justice information being collected as a part of the Federal drug effort, such as the strategies under development by the states; coordinate with other information gathering efforts; publish appropriate documents, such as a sourcebook for justice, drug-related statistics.

Grant Period: This award will be for twenty-four months.

Award Amount: One award, through Interagency Agreement, will be made in the amount of \$1,500,000 to BJS who will make an award to a non-profit organization for that amount.

Eligibility Criteria: The criteria for competitive selection will be the responsibility of the Bureau of Justice Statistics.

Due Date: Application for the Interagency Agreement will be due to the Bureau of Justice Assistance by April 1, 1987. Applications by non-profit organizations to BJS will be due on approximately April 1, 1987.

Program Contact: The Bureau of Justice Assistance contact for additional information is John Gregrich, Discretionary Grant Program Division, (202) 272-6838.

Authority: 1302 (1) (3) (6).

Program Title: NIJ-Drug Use Forecasting.

Background: Extensive research has been conducted by the National Institute of Justice, in two major cities over the past two years. This research was designed to determine the relative risk to the public resulting from pretrial release of drug using arrestees. One byproduct of this effort was the determination that drug use was much more prevalent than anticipated; over half of the arrestees at these two sites having used drugs just prior to arrest. The public policy implications of this finding alone require that testing be conducted more widely, to determine the degree to which the two sites tested are representative of the country as a whole.

Goal/Objective: This program will provide, to local, state and Federal

government, specific information on the prevalence and type of drug use among arrestees, in ten sites and by inference in the country as a whole.

Program Description: An Interagency Agreement will be awarded to the National Institute of Justice to support periodic urinalysis of arrestees, in ten sites, for the purpose of determining the prevalence of drug use and the kinds of drugs being used. This will provide a broader base of information, by which to determine whether the high rates of drug use in New York and Washington DC are representative of the nation as a whole. The NIJ will identify ten sites, test a representative sample of arrestees every three months for about a year and report on the findings. This effort is directly supportive of BJA efforts underway to document and transfer the testing approach employed in Washington, DC, and will contribute directly to the development of other testing efforts which are a part of this discretionary effort and which are envisioned in state block programs.

Grant Period: This award will be for eighteen months.

Award Amount: One award, through Interagency Agreement, will be made in the amount of \$600,000.

Eligibility Criteria: The Interagency Agreement will transfer the funds to the National Institute of Justice; criteria for site selection will be the responsibility of the National Institute of Justice.

Due Date: Application for the Interagency Agreement will be due to the Bureau of Justice Assistance by April 1, 1987.

Program Contact: The Bureau of Justice Assistance contact for additional information is John Gregrich, Discretionary Grant Program Division, (202) 272-6838.

Authority: 1302 (1).

Program Title: State Strategies Evaluation.

Background: The Sections of the Anti-Drug Abuse Act, which are administered by the Bureau of Justice Assistance, require each participating State to develop a statewide drug strategy. A data based strategy process is essential to maximize the impact of the program funds on the drug problem; but it also a substantial burden, given the dynamic state of information related to drugs and crime. Given the nature of the challenge facing state and local criminal justice systems, BJA is intent on providing assistance regarding strategy development and implementation.

Goal/Objective: This program will assist the states and the Bureau with the identification of existing data sources, the use of various data collection and

analysis techniques, and the evaluation of the impact of the statewide drug strategies.

Description: The BJA will negotiate a grant with the Criminal Justice Statistics Association to: provide technical assistance to the States in data collection and analysis techniques, design a scheme for the evaluation of the impact of statewide strategies on the drug problem and the criminal justice system; evaluate the strategy implementation in selected states to determine the factors which are critical to an effective approach to drug control; and develop criteria, based on these evaluations, which BJA should use in reviewing the state strategies.

Grant Period: This award will be for eighteen months.

Award Amount: One award will be made in the amount of \$250,000.

Eligibility Criteria: An award will be made to the Criminal Justice Statistics Association, on a non-competitive basis, due to the Association's unique qualifications and relationship with the Statistical Analysis Centers in the states.

Due Date: The application will be due to the Bureau of Justice Assistance by April 1, 1987.

Program Contact: The Bureau of Justice Assistance contact for additional information is Patricia Malak, Program Policy and Management Division, (202) 272-6838.

Authority: 1302 (2).

Project Title: Statewide Drug Prosecution Program.

Background: BJA is undertaking a Demonstration Program that is designed to enhance the ability of state and local criminal justice agencies to investigate and prosecute multi-jurisdictional narcotics trafficking crimes through the establishment of statewide prosecution capabilities. In many states, drug trafficking conspiracies and offenders do not contain themselves within one city, county, or judicial district. The diffusion of responsibility for organized criminals, at whatever level of sophistication, and narcotics control, among state and local jurisdictions, usually works to the advantage of the criminal groups. The enforcement and prosecution communities' response to the conspiracy/offense may be fragmented, duplicative, or limited resulting in the lack of prosecution or, at least, a reduction in the level or seriousness of the crimes prosecuted.

A formal mechanism whereby shared interdisciplinary resources are centrally coordinated coupled with the establishment of statewide prosecution capabilities can work to immobilize

targeted offenders who manage drug trafficking networks and organizations.

Goal/Objective: To develop statewide enforcement and prosecution projects to assist state and local law enforcement agencies to bring the full impact of state law to bear on specifically targeted narcotics trafficking conspiracies and offenders in states that have statutory authority to undertake statewide prosecutions but lack the necessary resources to initiate activities under these statutes.

Program Description: Up to six statewide enforcement/prosecution projects will be funded to develop and implement centrally coordinated multijurisdictional activities within a state to investigate drug trafficking conspiracies that cross jurisdictional lines of cities, counties, or judicial districts and to undertake statewide prosecutions. Emphasis will be placed on the enforcement of both civil and criminal state statutes that are similar to the Federal Racketeer Influenced and Corrupt Organizations (RICO) statute, the Federal Continuing Enterprise (CCE) statute, and Title I of the Federal Anti-Drug Enforcement. Emphasis will also be placed on a formal mechanism whereby investigative and prosecutorial resources can be allocated, focused, and managed against targeted drug traffickers. Critical to the success of this program is a shared management system of intergovernmental law enforcement/prosecutorial resources.

The Bureau of Justice Assistance will supplement an existing contract with the Institute for Intergovernmental Research (IIR) to provide technical assistance, management, and site selection criteria for this program.

Grant Period: Projects will be funded for 18 months with the expectation that they go through a 3-month organization and planning phase, and a 15-month implementation phase.

Eligibility Criteria: IIR will make its project site recommendations to BJA for final selection based on the following eligibility criteria:

a. The capacity of the participating agencies to conduct a complete and fully coordinated approach;

b. The presence of requisite legal authority coupled with willingness of executive officials to utilize available authority, as evidenced by:

(1) The presence of an attorney general, statewide prosecutor, or other prosecutorial official with statewide or multijurisdictional prosecutive authority, coupled with adequate available investigative authority;

(2) The presence of a special prosecution unit at the state level with appropriate operational experience in

prosecuting multijurisdictional or complex criminal conspiracy cases in areas such as narcotics trafficking, organized crime, financial or white collar crime, corruption, racketeering forfeiture, and related areas; and

(3) The presence of an office at the state level with criminal law jurisdiction either primary or concurrent with local prosecutors (district attorneys) in the investigation and trial prosecution of all criminal cases, or primary or concurrent selected trial level prosecution in multijurisdictional or complex cases (as specified above);

c. The existence of a coordinated approach to the narcotic crime problem, as evidenced by:

(1) Statutory authority or formal agreements coordinating local law enforcement/prosecutive agencies and efforts with State agencies and efforts; and

(2) Statutory authority or formal agreements coordinating investigative agencies and efforts with prosecutive agencies and efforts;

d. The availability of investigative resources and capabilities necessary to support prosecutive operations, as accomplished by either an appropriate statewide investigative authority or formalized agreement of coordinated local agency support to the statewide prosecutive effort;

e. Proposed criteria to be used in the selection and prosecution of cases, including jurisdictional definition of categories of criminal cases acceptable and criteria for level of significance and impact, whether by statute, mandate, or official policy; and

f. The anticipated impact on illicit drug conspiracies and the criminal justice system as measured by the level of drug related crime, criminal offenders, and criminal activity in such areas as seriousness, type, amount, and nature, along with outcomes, results, cases, arrests, prosecutions, convictions, recoveries, and asset seizures.

References: N/A.

Due Dates: Applications must be postmarked no later than April 15, 1987.

Contact Person: The BJA contact for additional information on this program is Richard H. Ward, Chief, Law Enforcement Branch (202/724-5974).

Authority: 1302 (2).

Program Title: Innovative Community Drug Offender Prosecution Program.

Background: Previous research, testing, demonstration and evaluation have documented that successful strategies to address crime problems related to drug abuse include the focusing of high intensity prosecutorial resources on: drug offenders (both users

and traffickers) who, directly or indirectly, contribute to a significant portion of crimes; areas of concentrated drug abuse activity; and on the reduction of drug trafficking in areas of high juvenile demand.

Goal/Objective: The goal of this program is to increase and disseminate experience with innovative community prosecutorial strategies and techniques so as to incapacitate offenders, who because of extensive drug usage and/or distribution activities, contribute significantly to the crime problem.

Program Description: This program incorporates the strategy of applying focused, well managed resources to target drug offenders (both users and traffickers), thereby averting a significant number of drug related crimes. Based upon accepted and innovative prosecutorial strategies/techniques, models will be fostered, and information resources and prosecutorial training programs will be established, to enable joint investigative and prosecutive agencies at the local level to identify, apprehend, and prosecute drug offenders. The program components will consist of modeling, and delivery of technical assistance and training services in support of the models. A field based organization, with expertise in criminal prosecution strategies and techniques, will be selected to conduct the modeling, participate in selection of local investigative and prosecutorial agencies through which strategies and techniques will be applied, arrange for delivery of supporting services, and coordinate evaluation.

Grant Period: This program will be eighteen months.

Award Amounts: A cooperative agreement will be awarded and the program will be funded in an amount up to \$1,500,000.

Eligibility Criteria: The field based organization described above should submit a concept paper of no more than 20 pages, including a one page budget summary, setting forth a menu of proposed program activities. Selection will be based upon how the field based organization responds to the following tasks:

- Design for implementing at least 6 workshops to provide operational and management training for a minimum of 160 prosecutors/investigators.
- Design for arranging on-site consultation and advice and information dissemination emphasizing use of peer practitioners and host sites to assist development and implementation of prosecution activities.

— Provisions for special reports, manuals, monographs, and other documents.

— Allocation of funds among the aforementioned tasks to achieve maximum program impact.

Due Dates: Concept papers will be due to BJA by May 1, 1987.

Program Contact: The BJA contact for additional information on this program is Jay Marshall, Discretionary Grant Program Division, (202) 272-4601.

Authority: 1302 (3).

Program Title: Training and Technical Assistance for Juvenile Court Judges.

Background: The National Council of Juvenile and Family Court Judges (NCJFCJ) in Reno, Nevada is the professional association of juvenile and family court judges in the 50 States. The association provides technical assistance and training to courts and court service personnel. The organization is professionally staffed and is recognized in the field as the leading training organization for juvenile courts. For the past five years the NCJFCJ has been provided with financial assistance from the Office of Juvenile Justice and Delinquency Prevention (OJJDP). The present grant from OJJDP has the following training objectives: (1) To supplement law school curricula which frequently provides only minimal training in juvenile and family law; (2) to provide judges with current information on important developments in juvenile and family case law and ever-changing, ever-increasing options for sentencing and treatment; and (3) to provide essential training to the juvenile practitioner's career. Technical assistance is also employed through the current grant and is provided through a written request for service. A survey recently conducted by the Council reveals that some form of substance abuse is involved in 60% of all family juvenile court cases while fewer than 15% of those juveniles were charged or adjudicated for such offenses. The judges in the survey indicated that the greatest need at present is the development and imposition of court ordered or court provided treatment services.

Goal/Objective: A drug abuse component and capability will be added to current activities of the NCJFCJ with particular emphasis on adjudication of drug abuse cases in the juvenile court. The new training and technical assistance component will address problems confronting the courts in handling this class of offenders and the development of means for ensuring intervention and treatment services.

Program Description: Additional funding to the National Council would

allow greater attention to the training and technical assistance needs of local juvenile and family courts. Current implementation procedures would be followed for technical assistance requests while additional training programs would be developed.

Grant Period: The award will be for 12 months.

Grant Award: A supplemental award of \$150,000 is proposed for a drug abuse component to the existing effort.

Eligibility Criteria: A supplemental award to the existing grant will be made to the National Council.

Due Date: Supplemental application will be due to BJA by July 1, 1987.

Program Contact: The BJA contact for additional information on this program is Jay Marshall, Discretionary Grant Program Division, (202) 272-4601.

Authority: 1302 (2) and (3).

Program Title: Adjudication Technical Assistance Program.

Background: States have elected to implement programs to reduce court delay, improve jury management, enhance use of jail capacity, prosecute habitual offenders, and expedite the adjudication of drug offenders using FY1985, FY1986, and FY1987 Block grant funds under the Justice Assistance Act of 1984 and the Anti-Drug Abuse Act of 1986. Assessments indicate jurisdictions continue to need technical assistance and training to achieve proper implementation of initial or enhanced programs. Current cooperative agreement with the Evaluation, Management and Training (EMT) Group, Inc. will not permit delivery of assistance during implementation of future programs.

Goal/Objective: This program is to provide for consultation and advice to enhance program development and implementation of adjudication programs.

Program Description: On-site and host-site consultation, information dissemination, and specialized training workshops will be available to eligible criminal justice agencies through FY1988. Emphasis will be given to those agencies receiving Block grant funds to implement prosecution, court, and jail management programs which target the drug offender. Secondary priority will be given to agencies using Block funds for such programs as Career Criminal Prosecution, Jail Capacity Management, Court Delay Reduction, and Jury Management Improvement.

Grant Period: This award will be for eighteen months.

Award Amount: One award, through cooperative agreement, will be made for up to \$750,000.

Eligibility Criteria: A supplemental award to the cooperative agreement will be made to EMT Group, Inc.

Due Date: Supplemental application will be due to BJA by July 1, 1987.

Program Contact: The BJA contact for additional information on this program is Jay Marshall, Discretionary Grant Program Division, (202) 272-4601.

Authority: 1302 (3).

Program Title: Comprehensive Drug Adjudication Program.

Background: Criminal Justice agencies must make informed and coordinated decisions regarding handling of drug abuse and drug trafficking offenders throughout the adjudicative process. Research, testing, and evaluation have supported the strategy that early identification/categorization of the offender and coordinated management of decision points affecting the offender as he/she moves through the process are critical to achieve proper and effective justice. Further, research continues to support deeper understanding of policy makers and drug abuse experts that information generated by drug testing can and should have direct strategic and tactical use by criminal justice agencies.

Goal/Objectives: The goal of this program is to achieve effective enforcement and deterrence of drug offenses through swift identification and handling of drug users and traffickers.

Program Description: This program consists of two components:

a. *Drug Testing Technology and Transfer.* Jurisdictions will be selected to demonstrate the widest practical application of information generated by drug testing of arrestees. It will build upon efforts now underway to document and transfer the testing program conducted by the Washington, D.C.

Pretrial Service Agency. Through cooperative agreement with the Pretrial Services Resource Center, the National Association of Pretrial Service Agencies (NAPSA) will conduct an assessment of the demonstration sites to ensure prudent and deliberate application of drug testing information and promote standards to guide jurisdictions considering the use of pretrial drug testing. Oversight of administration, assessment and technical assistance, including the development of site selection criteria, will be provided by the Pretrial Services Resource Center. BJA will retain authority to approve any agreement with the National Association of Pretrial Service Agencies and will select and award jurisdictions to serve as demonstration sites.

b. *Comprehensive Adjudication of Drug Offenders.* Jurisdictions will be selected to demonstrate a comprehensive model to expedite the

processing of drug offenders from initial charging through sentencing, by integrating services provided by prosecution, public defense, pretrial, court, and probation agencies. Urine analysis will serve as primary method for early identification of the addicted offender, determination of initial disposition, and continuous monitoring of the offender if placed in alternative to jail programs during pre and post trial stages. Emphasis will be given to rapid processing of offenders through accelerated prosecutorial screening, timely laboratory analysis, specially equipped drug courtrooms, and resources for intensive monitoring should the offender be released to alternative to incarceration programs. An evaluation will accompany this demonstration program keying upon effect of case processing delay reduction, results of drug monitoring and analysis, type and time disposition of cases, and impact of the program on drug abuse incidence within the participating jurisdictions. Oversight of administration, technical assistance, and evaluation, to include development of site selection criteria, will be performed by the Pretrial Services Resource Center under cooperative agreement. BJA will retain authority to approve any subaward agreement from the Pretrial Services Resource Center and will award grants separately to agencies selected as demonstration sites.

Grant Period: This program will be funded for eighteen months. Initial six months will be to develop final program elements, establish site selection criteria, and prepare selected site for program implementation.

Award Amount: Two to four grants will be awarded to demonstrate the Drug Technology and Transfer Program and three grants will be awarded to demonstrate the Comprehensive Adjudication of Drug Offenders Program. Each demonstration grant will be awarded in the range of \$750,000 to \$900,000 for a total of up to \$5,100,000. One cooperative agreement will be awarded to the Pretrial Services Resource Center for \$900,000.

Eligibility Criteria: The Pretrial Services Resource Center will provide for oversight, site selection criteria, technical assistance, site assessments and pretrial standards, and evaluation.

Due Dates: Application is due to BJA by May 15, 1987.

Program Contact: The BJA contact for additional information on this program is Jay Marshall, Discretionary Grant Program Division, (202) 272-4601.

Authority: 1302 (3).

Program Title: Differentiated Case Management.

Background: Research, development, and demonstration of court delay reduction techniques have been conducted by the National Institute of Justice and the Bureau of Justice Assistance, leading to the success of the Court Delay Reduction Program. Since the introduction of that program, a number of delay reduction techniques (i.e., weighted caseload, tracking) have been adopted to further promote case processing efficiency and effectiveness. Initial survey and research have identified one technique, differentiated case management, as the most promising tool for court systems and related agencies to coordinate and focus their management resources to expedite both criminal and civil cases.

Goal/Objective: The goal of this program is to expedite processing of criminal and civil cases, focused on the felony drug offender, through a coordinated management system.

Program Description: The strategy of the program is to ensure that handling of cases, which can be quickly or routinely expedited, is not affected by complex cases which can consume extraordinary time, attention and resources. Multiple tracks will be established in the court system (and parallel tracks in companion adjudication agencies) and management resources applied to promote expeditious handling of simple or routine cases. Activities of the program will include: initial analysis of individual cases to determine and arrange for adjudication resources, allocation of resources consistent with the analysis, coordination and application of resources when needed throughout the process, and intensive monitoring to keep the cases on schedule towards final disposition. Through this program, four demonstration sites will participate, implementing critical elements in both criminal and civil court systems. Technical assistance will be available to prepare sites for program implementation and to sustain operations. An evaluation will be conducted to determine achievement of program goals and national replication.

Grant Period: The award period will be for eighteen months.

Award Amount: The award amount, through cooperative agreement, will be for up to \$900,000. Of that amount, \$150,000 will be used to conduct evaluation and \$450,000 will be allocated for the 4 anticipated demonstration sites.

Eligibility Criteria: A cooperative agreement will be awarded to the

Evaluation, Management and Training (EMT) Group, Inc. to conduct program preparation activities, develop site selection criteria, award funds to agencies selected to implement program elements, and provide technical assistance in support of site preparation and implementation. The National Center for State Courts will conduct the evaluation. Sites will be selected by BJA and solicited to submit applications.

Due Date: Application is due to BJA by May 1, 1987.

Program Contact: The BJA contact for additional information on this program is Jay Marshall, Discretionary Grant Program Division, (202) 272-4601.

Authority: 1302 (3).

Program Title: Court Capacity Program.

Background: This program builds on previous research and development conducted by the National Institute of Justice and the Bureau of Justice Assistance to further define critical elements contributing to court delay and enhance performance capacity. Such research proves that court delay is not inevitable and can be controlled through applied, proven techniques. A second of the program is derived from previous work of the American Bar Association, Conference of State Court Administrators, and other national groups/commissions to establish performance standards for improving case flow and overall management of court operations.

Goal/Objective: The goal of this program is to promote systematic and permanent improvements in court operations, especially in large jurisdiction trial courts, so that these courts can provide fair and efficient adjudication of drug offenders.

Program Description: This program will conduct two separate, but interrelated projects. The first component will be to continue and expand case processing analysis of selected, large trial courts, provide delivery of focused technical assistance to those courts exhibiting high incidence of case backlog and/or processing delay, and document successful court systems which have achieved high performance in judicial management and quality of case disposition. The second component will focus on development and promotion of performance standards for trial and state courts relating to case processing and other judicial administrative responsibilities. A commission, representative of judicial leadership, will select measurable performance standards and oversee development and testing of an auditing strategy to

recognize those court systems achieving those standards.

Grant Period: This program will be funded for eighteen months.

Grant Amount: One grant award will be made for up to \$1,600,000.

Eligibility Criteria: This program will be conducted by the National Center For State Courts.

Due Date: Application will be due by May 1, 1987.

Program Contact: The BJA contact for additional information on this program is Jay Marshall, Discretionary Grant Program Division, (202) 272-4601.

Authority: 1302 (6).

Program Title: Baseline Management and Assessment Data (TASC).

Background: The growing body of research, on drugs, crime, and public safety, reaffirms the conceptual underpinnings of the Treatment Alternatives to Street Crime (TASC) program and documents its relative success in addressing drug-dependent offenders. New questions have been raised, however, by recent National Institutes of Justice research into the prevalence and nature of drug use by offenders. Reliable drug testing technology has found an incidence of drug use among arrestees twice as high as self-reports had indicated. This may be explained in part by the emergence of new drugs of choice, cocaine, and PCP, for which self-reports are least reliable. With monitoring and treatment programs already burdened by huge numbers, the possibility that half of the potential clients are going undetected and are abusing drugs which will require new treatment approaches is significant. The potential impact on public safety requires solid information on the resources available to the criminal justice system. In anticipation of these research findings, the BJA issued a purchase order, to the National Consortium of TASC Programs, to develop a data base collection instrument. It is now the intention of BJA to award a cooperative agreement for the collection of baseline management data.

Goal/Objective: This program will provide state and local criminal justice agencies and block grantees with specific information on case management resources for the monitoring and referral of drug-using offenders, and in doing so will provide baseline information from which to assess the impact of state anti-drug abuse strategies; and will provide a standard approach for the management and assessment of drug offender case management.

Program Description: Under a Cooperative Agreement, negotiated with

a national, field-based organization, expert in TASC, the data collection instrument, developed under Purchase Order #OJP-86-M-020, will be reviewed and revised as necessary, to respond to the mandates of the Anti-Drug Abuse Act and to the standards in the TASC Program Brief. The instrument will be used to gather, analyze and report information for TASC programs describing: the number of clients; the characteristics of clients; the number and type of staff; the duration of existence of the program; funding levels and sources; types of treatment programs available and frequency of use; the organizational affiliation of the program. The analysis will include a comparison of the number of clients referred to TASC at various points in the criminal justice system with the total criminal justice caseloads at those points. Highest priority for data collection will be given to sites under consideration for demonstration under this discretionary program.

Grant Period: The award will be for twelve months.

Award Amount: One award, through a negotiated Cooperative Agreement, will be made in the amount of \$100,000.

Eligibility Criteria: A Cooperative Agreement will be negotiated with a national, field-based organization, expert in TASC Programs.

Due Date: Application for the Cooperative Agreement will be due to the Bureau of Justice Assistance by April 1, 1987.

Program Contact: The Bureau of Justice Assistance contact for additional information is John Gregrich, Discretionary Grant Program Division, (202) 272-6838.

Authority: 1302 (6).

Program Title: Interim Treatment Program Assessment-Criminal History/TASC Linkage.

Background: Most research on treatment outcome has been done independently of the criminal justice system, and has therefore not taken advantage of certain existing resources. Almost all states now have repositories which maintain and disseminate official criminal history records, and in many states these records are automated. Extensive criminal justice use of criminal history information has required and resulted in substantial improvements in its quality. Security and privacy laws, which vary from state to state, limit access to these records for agencies other than criminal justice agencies. Thus agencies, like a local TASC program, which have long worked with or in response to criminal justice agencies, but are often private, non-

profit agencies, do not have benefit of access to criminal history records to inform screening, referral, treatment or monitoring decisions. The TASC program has been episodically evaluated over the last decade and found to effectively curtail the criminal and drug activity of clients while they are participating in the program. The long term impact of treatment referred to, are delivered, by TASC programs is less clearly established; although ongoing research indicates that the longer treatment participation, associated with TASC, results in improved post-treatment performance. This program is designed to draw upon criminal history records as a source of treatment outcome measurement.

Goal/Objective: This program will provide, to state and local criminal justice agencies and block grantees, specific information on the criminal activity of drug-dependent offenders, after they have completed a course of treatment; and will also provide model procedures for access to criminal history records.

Program Description: This program will conduct a five-part analysis and demonstration effort, the heart of which is a retrospective, longitudinal analysis of the criminal justice involvement of TASC clients after treatment. A Cooperative Agreement will be negotiated with SEARCH Group, Inc. to work with states which have both mature criminal history repositories and mature TASC programs to: analyze statutory obstacles to criminal history access; develop model procedures for access; conduct a longitudinal analysis of the post-treatment performance of TASC clients; recommend sites which can serve as sources of assistance to others; and, report on the utility of criminal history information in decisions regarding drug-dependent offenders.

Grant Period: This award will be for eighteen months.

Award Amount: One award, through a negotiated Cooperative Agreement, will be made in the amount of \$300,000.

Eligibility Criteria: A Cooperative Agreement will be negotiated with SEARCH Group, Inc.

Due Date: Application for the Cooperative Agreement will be due to the Bureau of Justice Assistance by April 1, 1987.

Program Contact: The Bureau of Justice Assistance contact for additional information is John Gregrich, Discretionary Grant Program Division, (202) 272-6838.

Authority: 1302 (3) and (6).

Program Title: Drug Testing Technology/Focused Offender Disposition Program.

Background: Research conducted and underway by the National Institute of Justice, continues to support a number of findings (e.g., drug use is a reliable predictor of pretrial misconduct, self-reports of drug use are not reliable, reliable technology is available). The same drug testing research which guides much of this discretionary program has highlighted certain areas of uncertainty and disagreement. The apparent success of monitoring as a deterrent to pretrial misconduct has led some to conclude that monitoring is an appropriate, general substitute for drug treatment. Others hold the view that monitoring, while an appropriate part of a treatment program, can promise no long term benefits. There is general agreement, however, regarding the dilemma faced by criminal justice decision-makers who deal with drug using offenders. In the simplest terms, most judges have great difficulty distinguishing among offenders (i.e., determining which are in need of and proper candidates for treatment).

Similarly, having decided on a treatment condition or referral, most judges have great difficulty distinguishing among treatment programs (i.e., which are credible in general, which one is right for this offender). This demonstration is designed to address these questions directly.

Goal/Objective: This program will provide specific, practical assistance to local, criminal justice decision-makers regarding the appropriate disposition of drug-using offenders, by providing and demonstrating specific guidelines for assessing offenders and available monitoring and treatment programs.

Program Description: This program will document and demonstrate the options available to the criminal justice system in dealing with the drug using offender, and will specifically address the relationship between treatment and monitoring. The demonstration will focus on up to four selected jurisdictions with a history of drug testing and a history of effective criminal justice system—treatment system cooperation, to document the most appropriate procedures and protocols for the determination of which offenders should be referred to monitoring and which should be referred to treatment and for the determination of the most appropriate criminal justice system role during the monitoring or treatment period. Appropriate national experts and organizations will be called upon to advise and recommend regarding: rigorous site selection criteria; essential site protocols; essential site data collection and analysis. Final products will include documented indicators and

protocols for effective disposition of drug using offenders. A Cooperative Agreement will be negotiated, with the National Association of State Alcohol and Drug Abuse Directors (NASADAD), to accomplish the necessary oversight, administration and assistance. BJA will retain the authority for approval of experts selected, for site selection criteria and for demonstration sites selected.

Grant Period: This award will be for twenty-four months.

Award Amount: One award, through a negotiated Cooperative Agreement, will be made, to include both oversight functions and site demonstrations. It is anticipated that up to four site demonstrations will be funded competitively, with a total of \$1,500,000 set aside for all demonstrations. The total award amount is \$2,000,000.

Eligibility Criteria: A Cooperative Agreement will be negotiated with the National Association of State Alcohol and Drug Abuse Directors (NASADAD). Criteria for competitive site selection will be developed and published by NASADAD. Sites will be invited to apply for participation in the demonstration. The Bureau of Justice Assistance will make final site selection, in accordance with published criteria.

Due Date: Application for the Cooperative Agreement will be due to the Bureau of Justice Assistance by April 1, 1987. Demonstration site competition is anticipated by August.

Program Contact: The Bureau of Justice Assistance contact for additional information is John Gregrich, Discretionary Grant Program Division, (202) 272-6838.

Authority: 1302 (4).

Program Title: Probation and Parole Narcotics Interdiction—National Training Program.

Background: This national scope research and training program was developed by the American Probation and Parole Association and the National Association of Probation Executives to strengthen the ability of probation and parole officers in detecting and treating drug abuse.

Goal/Objective: The program is designed to reduce the incidence of drug abuse and subsequent arrests or revocation of probation or parole. The objective is to provide probation and parole line officers with the knowledge and skills to detect drug use, assess severity, and learn techniques of surveillance, testing, and intervention. The grantee will document and disseminate successful models of drug screening, intervention and treatment, and the means of strengthening

relationships with community treatment agencies.

Program Description: This project will be divided into three phases:

(1) National search and documentation of successful probation/parole drug surveillance and intervention techniques, and successful models of probation/parole coordination with community treatment agencies;

(2) Development of a Training Manual for Probation/Parole agencies; and

(3) Training seminars for: Probation Executives; and Training Directors (training the trainers). Successful program models will also be disseminated to state legislative and executive officials.

Award Amount: \$300,000 is earmarked for this program for six regional seminars. One of the seminars may take place at the APPA annual institute.

Eligibility Criteria: One award will be made to a national, field-based organization experienced in probation and parole administration, under a cooperative agreement with BJA. This program will be for 24 months.

Due Dates: An application will be negotiated with a national organization in the period May 1 through May 15, 1987. Project start-up is scheduled for July 1, 1987.

Program contact: The BJA contact on this project is Nicholas Demos, Program Manager for Corrections, 202/272-4605.

Authority: 1302 (4).

Program Title: Intensive Supervision for Drug Offenders—Demonstration Program.

Background: BJA has already initiated an Intensive Probation Supervision Demonstration program, to include five projects, national technical assistance and training, and an independent evaluation. One of those demonstration projects involves intensive supervision of drug offenders. This will be an expansion of the program to involve an additional four Intensive Supervision projects for drug offenders.

Goal/objective: This program will initiate four additional intensive supervision units for drug offenders who are under probation or parole supervision. The objective is to reduce both drug recidivism and criminal activities of drug offenders through intensive supervision. The project is aimed at serious offenders who would normally show a high rate of recidivism.

Program Description: Each project would involve state-of-the-art risk/needs assessment, appropriate counseling/treatment services, and the elements of team supervision. Projects would allow for direct sentencing to intensive supervision, or transfer from

regular probation or parole caseloads based on fixed criteria. Each project would emphasize surveillance, urinalysis, and treatment standards. Projects may emphasize early intervention in prison or jail settings where probationers are serving a split sentence.

Four state or local Intensive Supervision sites will be selected by BJA for awards of \$150,000 per site. Grants will be awarded for a period of 18 months. Interested jurisdictions should submit a concept paper of approximately 10-12 pages plus a one-page summary budget.

Award Amount: \$750,000 has been earmarked for the four demonstration sites and the national technical assistance and training project.

Eligibility Criteria: Demonstration Sites. Eligibility criteria will include: probation/parole organizational plan; proposed sanction and control mechanisms; client screening system; local resources input; and replication potential.

An independent selection panel will screen concept papers and make recommendations to BJA on a competitive basis. Some weight will be given to geographical distribution of projects.

National Technical Assistance Grant: A national technical assistance organization experienced in probation and parole management will negotiate an 18 month Cooperative Agreement with BJA. \$150,000 has been set aside for technical assistance and evaluation purposes.

Applicants interested in providing technical assistance and evaluation should submit a concept paper of no more than 20 pages, including a one page budget summary. Selection will be based upon how well the applicant responds to the following tasks:

- Design for implementing workshops to provide operational and management training;
- Design for providing on-site consultation and information dissemination to assist development and implementation of Intensive Probation sites;
- Design for administrative oversight of sites selected for Program demonstration to include assessment and coordination of services;
- Provisions for special reports, manuals, monographs, and other documents; and
- Design of a simple independent evaluation which provides some impact assessment of demonstration sites.

References: "Granting Felons Probation: Public Risks and Alternatives", National Institute of Justice study by Rand Corporation, January, 1985.

"Intensive Supervision Program: Report to the Judicial College", New Jersey Administrative Office of the Courts, November, 1985.

"Taking Quality into Account: Assessing the Benefits and Cost of New Jersey's Intensive Supervision Program", Institute for Criminal Research, Rutgers University, 1986.

"New Dimensions in Probation: Georgia's Experience with "Intensive Probation Supervision (IPS)", National Institute of Justice Report, January, 1987.

Due Dates: Concept papers from interested jurisdictions are due at BJA by April 30, 1987.

Program Contact: The BJA contact for information on this program is Kim Rendelson, Corrections Program Specialist, 202/272-4605.

Authority: 1302 (4)&(6)

Program Title: Drug Related Program Development Assistance and Training

Background: Numerous evaluations have found treatment for drug-dependent offenders to be most effective when there is direct criminal justice involvement. The threat of criminal justice sanction motivates offenders to enter treatment and, perhaps more important, motivates them to stay in treatment for a period of time sufficient for behavior change. Treatment Alternatives to Street Crime (TASC) programs have fared well in these evaluations and in the assessment of local jurisdictions; over 100 such programs continued during the hiatus of Federal funding, during the early 1980s. In response to this track record, the Congress has seen fit to include TASC, specifically, in both the Justice Assistance Act and the Anti-Drug Abuse Act. In supporting this program, the BJA has found it to be well-evaluated but erratically documented; thus, initial program development and assistance efforts pursued, and have been guided by, a documentation of the core elements that make up the most effective local TASC programs and of the data collection necessary to manage and assess monitoring and referral of drug-dependent offenders.

Goal/objective: To continue to provide to local and state criminal justice agencies and to block grantees necessary technical and program development assistance and training.

Program Description: This program will supplement and expand the existing cooperative agreement with the National Association of State Alcohol

and Drug Abuse Directors (NASADAD), to assist criminal justice agencies and block grantees. It will build on efforts and documents completed and underway (i.e. the TASC Program Brief, operations manual, training manual, urinalysis monograph) and will focus primarily on the needed areas of cooperation and focused case management between the criminal justice system and the other social service system dealing with drug using offenders. TASC will remain the case management model. Anticipated areas of priority, in addition to one-site assistance, include the development and application of: quantitative performance standards; a site assessment protocol; an updated technical assistance resource catalog; a TASC program design for juvenile offenders; monographs on institutional aftercare, mentally ill offenders, recommended program outcome measures; periodic summarization and dissemination of relevant drug-crime research.

Grant Period: This award will be for twenty-four months.

Award Amount: A supplemental award, to the existing Cooperative Agreement, will be negotiated in the amount of \$500,000.

Eligibility Criteria: The Cooperative Agreement will be negotiated with the National Association of State Alcohol and Drug Abuse Director (NASADAD).

Due Date: Application for the Cooperative Agreement will be due to the Bureau of Justice Assistance by April 1, 1987.

Program Contact: The Bureau of Justice Assistance contact for additional information in John Gregrich, Discretionary Grant Program Division, (202) 272-6838.

Authority: 1302(4).

Program Title: Comprehensive State Department of Corrections Treatment Strategy for Drug Abuse.

Background: Many state departments of corrections will need assistance in expanding and upgrading drug treatment and rehabilitation programs. New York State Department of Correction Services in cooperation with narcotics and Drug Research, Inc., a non-profit agency, has extensive experience in developing statewide drug treatment activities.

Goal/objective: This program will assist state departments of corrections to develop comprehensive institutional drug treatment and rehabilitation components on a statewide basis. The purpose is to develop or update a statewide corrections strategy for dealing with drug offenders based on the latest research and the best of current state models.

Program Description: The program will be implemented in two phases, to include:

- a. A three to six month comprehensive planning and organization effort for the design of institutional drug treatment and rehabilitation; and
- b. An 18-month implementation effort for those state departments of corrections that show the highest promise and support for a statewide drug treatment initiative.

Planning Phase (3 to 6 months). Five to six state departments of corrections will be assisted in developing various models for comprehensive drug treatment and rehabilitation. A national program coordinator will oversee the planning phase, and administer sub-grants of \$75,000 to \$125,000 per state. The national program coordinator will also provide general clearinghouse service to other requesting state departments of corrections. \$600,000 has been earmarked for this component.

Implementation Phase (18 month). States that complete the planning process on which have already developed comprehensive drug treatment plans on their own can compete for three implementation grants of up to \$400,000 each. States are encouraged to review the status of their plans with the BJA Corrections Program Manager prior to submission of a full application.

1,200,000 has been earmarked for this component.

National Program Coordinator. The Narcotics and Drug Research, Inc. (NDRI), Albany, New York, has been selected as national program coordinator for this program. NDRI was selected because of the outstanding reputation of its 50-person staff and as the winner in a recent NIJ competition for the Drugs in Crime Center project.

Award Amount: \$2,200,000 has been earmarked for this program. A 24-month cooperative agreement will be negotiated with Narcotics and Drug Research, Inc., Albany, New York, for \$1,000,000, to include \$600,000 for the planning phase sites, and \$400,000 for technical assistance and administration.

\$1,200,000 has been earmarked for three implementation sites to be selected in a competitive process.

Eligibility Criteria: *Planning Phase.* Interested jurisdictions should submit a concept paper of approximately 10-12 pages plus a one page summary budget. Eligibility criteria will include:

- Analysis of range and scope of current drug addiction in the inmate population; proposed department organizational plan; proposed screening system; State resources available for implementation

(including federal Block Grant funds); and replication potential for other States.

—An independent selection panel will screen planning phase papers and final applications and make recommendations on a competitive basis. Some weight will be given to geographical distribution of projects.

References: "Outcome Evaluation of A Prison Therapeutic Community for Substance Abuse Treatment: Preliminary Results", H. Wexler, D. Lipton, & K. Foster, Narcotic & Drug Research, Inc., Paper for American Society of Criminology, Nov., 1985.

Due Dates: *Planning Phase.* Concept papers from interested State departments of corrections are due at BJA by April 20, 1987. Sites will be selected by May 15, 1987, and contracts with the national program coordinator should be completed by June 30th.

Implementation Phase. Complete applications on Federal SF 424 are due at BJA by September 30, 1987. Each application should include a complete budget, a workplan based on the planning phase, and the proposed organization and support services available for its drug rehabilitation strategy.

Program Contact: The BJA contact for this program is Nicholas Demos, Program Manager for Corrections, 202/272-4605.

Authority: 1302 (4).

Program Title: Model State Prison Industry—Drug Rehabilitation Project.

Background: This program emanated from discussions with a prison industries planning group and officials of the Correctional Industries Association, the professional organization representing State prison industries. The officials believe that drug treatment and rehabilitation can be reinforced by effective prison work, and that purposeful work and drug treatment go hand in hand. This project will be an added component to the present Prison Industry Information Clearinghouse at the American Correctional Association.

Goal/Objective: This program will develop effective drug treatment and rehabilitation components within a model prison industry setting. The purpose is to demonstrate that drug treatment and rehabilitation can take place in a modern prison industry setting, benefiting the inmate, the department of corrections, and the public. It is based on the theory that drug education and treatment activities and purposeful work have a synergistic effect on the inmate, and offer a greater chance of changed behavior than non-work programs.

Program Description: One model project would be developed by a State department of corrections in coordination with the prison industry division. The project would combine model drug education and treatment components within a modern prison work setting. The prison work activities and the drug treatment activities should be closely coordinated to insure maximum impact. The prison industry should incorporate modern business and work practices, and incentive wages to the extent practical. The project should insure continuity of care by insuring follow-up in community drug treatment and services agencies.

One demonstration site will be selected for a direct grant of \$400,000 to develop a model State prison industry-drug rehabilitation project. The grant will be for an 18-month period. Selection will be on a competitive basis.

One cooperative agreement will be completed with the American Correctional Association for \$100,000, as a supplement to the current Correctional Industry Information Clearinghouse. The ACA will be responsible for technical assistance and documentation, and for an independent evaluation of the demonstration site. A cooperative agreement will be negotiated in June, 1987.

Award Amount: \$500,000 is earmarked for this program. \$400,000 is for a direct grant to the selected State, and \$100,000 is for technical assistance and evaluation purposes.

Eligibility Criteria: Interested State departments of corrections should submit a complete application on SF 424. Applications should define the elements of drug rehabilitation and treatment components as well as the prison industry component, and describe the integration of all services at the institution, as well as aftercare services.

Eligibility criteria will include: Innovations in the integration of prison industry and drug treatment and rehabilitation components; intensity and comprehensiveness of the treatment modules; proposed inmate work skills and business practices covered in the prison industry; and level of State support and commitment to prison industry-drug treatment model.

Due Dates: Applications are due at BJA by June 15, 1987. The projected start-up date is July 30, 1987.

Program Contact: The BJA contact for this program is Nicholas Demos, Program Manager for Corrections, 202/272-4605.

Authority: 1302 (4).

Program Title: Technical Assistance to Corrections Agencies.

Background: State departments of corrections and local jails and community corrections agencies will be implementing a wide range of drug screening, drug treatment and rehabilitation projects with State Block Grant funds. Many of these new or expanded drug-related projects will have a significant impact on the operations of correctional agencies, and there will be substantial need for technical assistance and training to support these projects.

Goal/Objective: This Technical Assistance project is designed to provide a range of site-specific technical assistance and training in support of new Block Grant and non-Block Grant projects in correctional institutions and in community corrections agencies. In addition, it will support BJA-initiated special projects.

Program Description: One technical assistance grant will be awarded to a national consulting firm or agency to implement the technical assistance and training activities. It is projected that 6-8 regional or State seminars will be implemented on special topics related to drugs, such as special handling of drug dealers, eliminating drugs in the institution, model personnel and job descriptions, etc. It is projected that up to 60 on-site technical assistance assignments will be completed, covering drug treatment, organization, management, and screening instruments.

Implementation will be primarily on a broker basis, i.e., maximum use will be made of experienced administrators, practitioners, and consultants. Twenty-five percent (25%) of grant funds should be earmarked for special projects at the direction of BJA.

Award Amount: \$350,000 is earmarked for this project.

Eligibility Criteria: One eighteen-month national scope technical assistance cooperative agreement will be awarded on a competitive basis. Interested firms or non-profit agencies should complete a Federal SF 424 application to include complete budget, staff capabilities, experience with technical assistance and training for corrections (including drug treatment), proposed method of consultant networking, and quality control for technical assistance assignments.

An independent panel will screen and rank applications based on the following criteria: Expertise of staff in conducting technical assistance and training for corrections agencies, including expertise in drug treatment in the corrections setting; quality of performance workplan; and proposed use of funds to achieve maximum delivery of assistance.

Due Dates: Applications are due at BJA by April 15, 1987. Project start-up is proposed for May 15, 1987.

Program Contact: The contact for this program is Nicholas Demos, Program Manager for Corrections, 202/272-4605.

Authority: 1302 (6).

Program Title: Drug Treatment for Individual State Corrections Institutions—Demonstration Program.

Background: This program is designed for institutions where the State may not be ready to implement a comprehensive statewide strategy, but where an innovative pilot project is ready for implementation. This program is complementary to the Comprehensive State Strategy Program, and is designed for those states where a comprehensive state strategy may not be feasible, but where an innovative pilot drug treatment and rehabilitation model is ready for implementation at one institution.

Goal/Objective: The program is designed to test a variety of drug treatment and rehabilitation modules at individual State institutions (prisons, institutional mental health or drug treatment facilities).

Program Description: Six grants will be awarded to states that wish to develop a pilot drug treatment and rehabilitation project at one facility. States that are selected for the Comprehensive State Department of Corrections Treatment Strategy would not be eligible for this program. Since federal funding would not be sufficient to cover the costs of the entire program, these funds should be viewed as incentive funds that can help with treatment staff, planning, and minor equipment costs. Discretionary funds should be combined with State Block Grant funds and State funds to finance a comprehensive institutional program.

Each applicant site will prepare a concept paper of approximately 10-12 pages plus a one-page budget summary. The concept paper should outline the existing environment for drug screening and treatment, the proposed facilities and staff to be used, modules for treatment, and expected outcomes. Some preferences will be given to therapeutic community and residential group treatment and there will be an emphasis on continuity of care. Each project will provide for its own evaluation.

Award Amount: \$900,000 is earmarked for this demonstration program. Six direct grants of up to \$150,000 per project will be made. Grants will be for a period of 18 months.

Eligibility Criteria: Up to six grants will be awarded to State departments of

corrections for implementation at single institutions. Eligibility criteria will include: Analysis of the range and scope of current drug addictions in the institution's inmate population; proposed screening system; institutional resources available for implementation (federal Block Grant and State funds); and replication potential for other institutions.

An independent selection panel will screen concept papers and make recommendations on a competitive basis. Final sites will be selected by BJA. Some weight will be given to geographical distribution of projects.

References: (See previous program, Comprehensive Corrections Treatment Strategy).

Due Dates: Concept papers are due at BJA by June 15, 1987.

Program Contact: The BJA contact for this program is Kim Rendelson, Corrections Program Specialist, 202/272-4506.

Authority: 1302 (6).

Program Title: Drug Treatment in the Jail Setting—National Demonstration Program.

Background: The American Jail Association proposed a national research and demonstration program to assist jails and community corrections agencies in improving screening and treatment for drug offenders. This program is an outgrowth of that proposal.

Goal/Objective: This program will assist local jails and community corrections agencies to improve their drug screening and treatment services, and develop two national models for possible replication. The emphasis will be on drug treatment in larger metropolitan jails, but training and clearinghouse services will be provided for smaller jails as well.

Program Description: This program is divided into four components:

(1) A survey of current jail drug treatment programs, updating a study by Newman and Price from the 1970's;

(2) Development of two pilot projects which incorporate a comprehensive model for jail and community drug treatment and drug offenders;

(3) Transfer of project components from the model jails to other metropolitan jails through documentation and host visits; and

(4) Preliminary research on success in reducing drug abuse and recidivism rates through a combination of institutional and community treatment.

Two pilot projects to be selected by an independent expert panel and approved by BJA will each receive contracts of up to \$300,000 each to implement their project. \$300,000 is set

aside for administration, technical assistance, and the preliminary research component.

Award Amount: \$900,000 is earmarked for this program.

Eligibility Criteria: Eligibility criteria will include: Level of integration of jail and community treatment components; comprehensiveness of the drug treatment component; support from local correctional and drug treatment officials; and local funding sources committed to the project. Projects are encouraged to combine Block Grant and Discretionary funds if possible.

A national, field-based organization expert in jail administration will be the National Program Coordinator for this program. A Cooperative Agreement of \$300,000 will be negotiated.

Due Dates: Concept papers from interested metropolitan jails should be submitted to BJA by June 30, 1987. An independent panel will screen and recommend the two demonstration projects. BJA will make the final selection and solicit applications by July 30. A start-up date of August 1, 1987, is proposed.

Program Contact: The BJA contact for this program is Kim Rendelson, Corrections Program Specialists, 202/272-4605.

Authority: 1302 (4)&(6).

Program Title: Model Treatment Programs/Documentation.

Background: Research and evaluations conducted by the National Institute of Justice, the National Institute of Juvenile Justice and Delinquency Prevention, the National Institute of Drug Abuse and by other federal agencies have continued to indicate that treatment can be effective, especially when fostered by the threat of criminal justice sanction and when pursued for sufficient duration. However, many, apparently effective programs have proven quite difficult to evaluate. This program is designed to enable the Bureau of Justice Assistance to: provide a disciplined response to the numerous programs that have been recommended for funding; and to provide responsible guidance to states and localities regarding the programs available to them.

Goal/Objective: To provide direct assistance to state and local criminal justice agencies and block grantees, through the identification and documentation for transfer of effective treatment programs for drug-dependent offenders.

Program Description: Through a negotiated Cooperative Agreement with the National Criminal Justice Association (NCJA), the BJA will draw upon experts in treatment, in evaluation

and in criminal justice to identify and document for transfers effective programs which treat drug-dependent offenders. Programs will be reviewed in light of specific criteria, to be developed through the Cooperative Agreement. Treatment programs which can demonstrate effectiveness will be documented in Treatment Programs Briefs. NJCA will administer this process, including the documentation of effective treatment program, through the development of program briefs. BJA will retain the authority for final selection of programs to be documented.

Grant Period: This award will be for twenty-four months.

Award Amounts: One award will be made, through a negotiated Cooperative Agreement, for administration of the conduct of program review, program documentation, and program brief development and dissemination, in the amount of \$500,000.

Eligibility Criteria: A Cooperative Agreement will be negotiated with the National Criminal Justice Association (NCJA).

Due Date: Application for the Cooperative Agreement will be due to the Bureau of Justice Assistance by April 1, 1987.

Program Contact: The Bureau of Justice Assistance contact for additional information is John Gregrich, Discretionary Grant Program Division, (202) 272-6838.

Authority: 1302 (7).

Program Title: Organized Crime/Narcotics Trafficking Enforcement Program.

Background: A clear picture of the changing nature of organized crime emerged from the records of the President's Commission on Organized Crime.

Its methods are brutal, and its scope is pervasive.

The principle income-generating activity for organized crime is the production and distribution of illegal drugs, at \$80 billion a year.

Development of successful cases against organized crime narcotics trafficking conspiracies requires utilization of unique investigative techniques. Civil and criminal forfeiture of assets are now recognized by law enforcement as an effective means of depriving illicit drug traffickers of economic support and incentive. A formal mechanism whereby shared interdisciplinary resources are centrally coordinated can work to immobilize targeted offenders who manage these networks and organizations.

Goal/Objective: To develop regional enforcement projects to assist state and

local law enforcement agencies through joint operations with Federal personnel and to remove specifically targeted major organized crime narcotic trafficking conspiracies and offenders through investigation, arrest, prosecution, asset forfeiture and conviction.

Program Description: Up to 10 new regional enforcement projects will be funded to develop and implement centrally coordinated multijurisdictional activities to investigate and prosecute complex multistate crimes and their perpetrators. Emphasis will be on establishment of an interdisciplinary response to commonly shared major crimes related to drug trafficking throughout a regional area and a formal mechanism whereby investigative and prosecutorial resources can be allocated, focused, and managed against targeted offenses and high level offenders to achieve maximum criminal and civil remedies. Critical to the success of this program is a shared management system of intergovernmental law enforcement/prosecutorial resources.

The Organized Crime/Narcotics Trafficking Demonstration Program currently funded under the Justice Assistance Act Discretionary Program will be supplemented and expanded. Certain sites will receive additional operating funds, new sites will be developed, and a financial investigation component will be added. It should be noted that this program has been coordinated with the DEA Drug Enforcement Task Forces and the Department of Justice Organized Crime/Drug Enforcement Task Forces and has been designed to complement other ongoing Federal activities as appropriate.

The Bureau of Justice Assistance will accomplish this demonstration through a cooperative agreement with the Institute for Intergovernmental Research as explained below under Eligibility Criteria.

Grant Period: The new projects will be funded for 18 months with the expectation that they will go through a three-month organization and planning phase, and a 15-month implementation phase.

Award Amounts: Up to a total of 20 awards are estimated in a range of between \$200,000 and \$600,000.

Eligibility Criteria: Potential applicant agencies will be identified by the Institute for Intergovernmental Research (IIR) based on their observed capacity to conduct a complete and fully coordinated demonstration program in areas in which there is a high incidence of drug abuse and drug trafficking to identify major drug offenders and move

these offenders expeditiously through the judicial system. Of these agencies identified, BJA will make final site selection based on the following criteria:

- Joint agency management and direction of investigations and prosecutions including the presentation of signed formal intergovernmental agreements;
- A coordinated approach to the crime problem which results in a major impact on illicit drug trafficking not achievable through a single agency case by case approach;
- Standardized procedures for central collection and dissemination of information, for joint case administration, and for investigative techniques and approaches;
- Organizational and staffing plan;
- The proposed case threshold or selection criteria to be used in the selection and prosecution of complaints; and
- Anticipated impact upon the criminal justice system and on the illicit drug problem.

References: N/A.

Due Dates: Since these funds will be contracted by IIR to BJA selected sites, after completion of the above described process, no due dates are being announced.

Contact Person: The BJA contact for additional information on this program is Richard Ward, Chief, Law Enforcement Branch, 202/724-5974.

General Requirements:

Match: Grants may be awarded for up to 100 percent of program or project costs.

Eligibility: Public agencies and private non-profit organizations are eligible to apply. Specific eligibility requirements will be set forth in individual announcements.

Period of Support: Grants may support projects for up to three years.

Financial Requirements: Discretionary grants are governed by the provisions of the Office of Management and Budget (OMB) Circulars applicable to financial assistance. The Circulars along with additional information and guidance are contained in the "Financial and Administrative Guide for Grants" OJP Guideline Manual, OJP M71001C, available from the Office of Justice Programs.

Non-Discrimination: The Justice Assistance Act provides that no person shall be excluded from participation in, denied the benefits of, subjected to discrimination under, or denied employment in connection with any activity funded in whole or in part with funds made available under the Act. Applicants for discretionary grants are

also subject to the provisions of the Title VI of the Civil Rights Act of 1964; section 504 of the Rehabilitation Act of 1973, as amended; Title XI of the Education Amendments of 1972; the Age Discrimination Act of 1975; and the Department of Justice Non-Discrimination Regulation 28 CFR Part 42, Subparts C, D, E, and G.

Benjamin H. Renshaw,

Acting Director.

[FR Doc. 87-5977 Filed 3-18-87; 8:45 am]

BILLING CODE 4410-18-M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Prohibited Transaction Exemption 86-128]

Class Exemption for Securities Transactions Involving Employee Benefit Plans and Broker-Dealers

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of effective date of Prohibited Transaction Exemption 86-128 and extension of the revocation date of Prohibited Transaction Exemption 79-1 and Prohibited Transaction Exemption 84-46.

SUMMARY: This document contains the effective date for Prohibited Transaction Exemption 88-128 (51 FR 41686) and a revised revocation date for Prohibited Transaction Exemption 79-1 (44 FR 5963) and Prohibited Transaction Exemption 84-46 (49 FR 22157).

Prohibited Transaction exemption 86-128 allows persons who serve as fiduciaries for employee benefit plans to effect or execute securities transactions under certain circumstances. The exemption also allows sponsors of pooled separate accounts and other pooled investment funds to use their affiliates to effect or execute securities transactions for such accounts when certain conditions are met. The effective date provision of Prohibited Transaction Exemption 86-128 provided for an effective date of the later of December 18, 1986, or the date on which the Office of Management and Budget approved the information collection requests in the exemption under the Paperwork Reduction Act of 1980. The Department stated in the preamble to the exemption that it would publish a notice in the **Federal Register** notifying interested persons when the exemption became effective. This notice serves that purpose. It also provides for a postponement of the effective date of revocation of the two other Prohibited

Transaction Exemptions referred to above until June 1, 1987.

EFFECTIVE DATES: The effective date of Prohibited Transaction Exemption 86-128 is February 12, 1987. Prohibited Transaction Exemptions 79-1 and 84-46 are revoked effective June 1, 1987.

FOR FURTHER INFORMATION CONTACT: Daniel J. Maguire, Esq., Plan Benefits Security Division, Office of the Solicitor, U.S. Department of Labor, Washington, DC 20210, (202) 523-9595 (not a toll free number) or Mark A. Greenstein, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, (202) 523-8671 (not a toll free number).

SUPPLEMENTARY INFORMATION: On November 18, 1986, the Department of Labor (the Department) published a notice in the **Federal Register** (51 FR 41686) containing the grant of Prohibited Transaction Exemption 86-128, which exempts certain transactions from the restrictions of section 406(b) of the Employee Retirement Income Security Act of 1974, and from the taxes imposed by section 4975 (a) and (b) of the Internal Revenue Code (the Code) by reason of Code section 4975(c)(1) (E) or (F). That notice also contained a provision [Section VI(b)] for the revocation of Prohibited Transaction Exemptions 79-1 and 84-46 effective April 1, 1987.

The Office of Management and Budget has approved the paperwork requests contained in Prohibited Transaction Exemption 86-128 effective February 12, 1987 and has approved them for use through February 29, 1988. In addition, the Department has decided to extend the revocation date of Prohibited Transaction Exemptions 79-1 and 84-46 from April 1, 1987 to June 1, 1987 so as to allow authorized persons and authorizing fiduciaries sufficient time in which to adjust their authorization and reporting procedures.

A complete discussion of the transitional rules relating to these exemptions can be found in the preamble to Prohibited Transaction Exemption 85-128 (51 FR 41694).

Notice of effective Dates

Notice is hereby given that the Office of Management and Budget (OMB) has approved the information collection requests under the Paperwork Reduction Act of 1980 for Prohibited Transaction Exemption 86-128 (published at 51 FR 41686, November 18, 1986), which exempts certain transactions from the restrictions of section 406(b) of the Employee Retirement Income Security Act of 1974 and from the taxes imposed by section 4975 (a) and (b) of the

Internal Revenue Code (the Code) by reason of Code section 4975(c)(1) (E) or (F). The date of OMB approval was February 12, 1987 and thus the effective date of Prohibited Transaction Exemption 86-128 is February 12, 1987. The information collection requests under Prohibited Transaction Exemption 86-128 have been assigned OMB control number 1210-0059 and are approved for use through February 29, 1988.

Notice is also hereby given that the revocation date for Prohibited Transaction Exemption 79-1 and Prohibited Transaction Exemption 84-46 has been extended from April 1, 1987 to June 1, 1987.

Signed at Washington, DC, this 11th day of March 1987.

Dennis M. Kass,

Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 87-5868 Filed 3-18-87; 8:45 am]

BILLING CODE 4510-29-M

NATIONAL SCIENCE FOUNDATION

Privacy Act of 1974; Amendment of System of Records

Notice is hereby given of an amendment to NSF System of Records No. 6, entitled "Doctorate Records File," as published in *Privacy Act Compilation of 1985*, Vol. V, p. 217. Changes are being made to list the system as jointly owned by the National Science Foundation and the Department of Education, National Endowment for the Humanities, and National Institutes of Health, with the National Science Foundation being the controlling agency, and to amend the system location and uses to reflect this joint ownership. Interested persons are invited to submit written data, views or arguments to the Director, National Science Foundation, Attn: NSF Privacy Act Officer, 1800 G Street NW., Washington, DC 20550, within 30 days from the publication of this notice.

NSF-6

SYSTEM NAME:

Doctorate Records File.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Academy of Science, 2101 Constitution Avenue NW., Washington, DC 20418; National Science Foundation, 1800 G Street NW., Washington, DC 20550; Department of Education, 400 Maryland Avenue, SW., Washington, DC 20202; National Endowment for the Humanities, 1100 Pennsylvania Avenue

NW., Washington, DC 20506; and National Institutes of Health, Buildings 1 and 12, 9000 Rockville Pike, Bethesda, MD 20892.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system includes individuals who have received earned doctorates from U.S. institutions since 1920. Limited information (name, field of degree and institution) on persons receiving doctorates between 1920 and 1958 was compiled from public records. Information for persons receiving degrees after 1958 has been supplied voluntarily by the person receiving the degree. Some institutions supply name and field of degree for persons not providing any information.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Social Security Number, birth date, sex, citizenship, race, education history, sources of financial support during graduate study, postgraduation plans.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section I (3)(a)(6), (4)(j)(1) (42 U.S.C. 1862); Section II (37) (42 U.S.C. 1885d); National Science Foundation Act of 1950 as amended.

PURPOSES:

This system is used:

1. To provide a source of information on demographic and educational characteristics and employment plans of recipients of doctorates from American universities, in compliance with Foundation responsibilities to monitor scientific and technical resources.
2. To provide indicators of the state of science and engineering in the United States, as required by congressional mandate.
3. To report biennially on the participation of men and women by race and by ethnic group and by discipline, in scientific and technical fields, as required by congressional mandate.
4. To provide the sampling frame for the survey of doctorates in the Scientific and Technical Personal Data System for the Foundation.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Information is given to the institution awarding degree, but only for its own doctorates.
2. Disclosure may be made to the federal sponsors listed under "System location" above, their contractors and collaborating researchers and their staff for the purpose of analyzing data and

preparing scientific reports and articles in order to accomplish the research purpose for which the records are collected. All users of the system are required to comply with the requirements of the Privacy Act with respect to such records.

3. Records are disclosed to the National Institutes of Health for review and evaluation of its programs.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Computer tapes and questionnaires are kept by the National Academy of Sciences. Computer tapes are kept by the National Science Foundation, Department of Education, National Endowment for the Humanities, and the National Institutes of Health.

RETRIEVABILITY:

Alphabetically by last name of individual.

SAFEGUARDS:

Data are kept in secured areas with access limited to authorized personnel. Questionnaires, in paper copy or in microfiche, are kept in locked cabinets. Published findings are in formats which preclude individual identification.

RETENTION AND DISPOSAL:

Computer tapes are kept indefinitely by the National Academy of Sciences for use by the project in fulfilling its responsibilities described above under "Purposes".

SYSTEM MANAGER(S) AND ADDRESS:

Division Director, Science Resources Studies, National Science Foundation, 1800 G St. NW., Washington, DC 20550.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the system manager and provide the following information.

1. System Name: Doctorate Records File

2. Complete name at time degree was awarded

3. Complete birth data and institution awarding degree (to distinguish among duplicate names, if necessary).

RECORD ACCESS PROCEDURES:

See "Notification Procedure" above.

CONTESTING RECORD PROCEDURES:

See "Notification procedure" above.

RECORD SOURCE CATEGORIES:

Information obtained voluntarily from individual.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Dated: March 16, 1987.

Herman G. Fleming,

NSF Reports Clearance Officer.

[FR Doc. 87-5939 Filed 3-18-87; 8:45 am]

BILLING CODE 7555-01-M

Advisory Panel for Ecology; Meeting

The National Science Foundation announces the following meeting:

Name: Advisory Panel for Ecology.

Date and Time: April 2 and 3, 1987—8:30 a.m. to 5:00 p.m. each day.

Place: Room 1242, National Science Foundation, 1800 G Street, NW., Washington, DC 20550.

Type of Meeting: Closed.

Contact Person: Dr. Patrick W. Flanagan, Program Director, Ecology (202) 357-9734, Room 215, National Science Foundation, Washington, DC 20550.

Summary Minutes: May be obtained from the Contact Person at the above address.

Purpose of Meeting: To provide advice and recommendations concerning support for research in ecology.

Agenda: Review and evaluation of research proposals and projects as part of the selection process of awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

M. Rebecca Winkler,

Committee Management Officer.

March 16, 1987.

[FR Doc. 87-5935 Filed 3-18-87; 8:45 am]

BILLING CODE 7555-01-M

Advisory Committee for Industrial Science and Technological Innovation; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the National Science Foundation announces the following meeting.

Name: Advisory Committee for Industrial Science and Technological Innovation.

Date and Time: April 8, 1987; 8:30 a.m.—5:00 p.m.

Place: National Science Foundation, 1800 G Street, NW., Room 642, Washington, DC 20550.

Type of Meeting:

Contact Person: Mrs. Carolyn J. Smith, Administrative Officer, Division of Industrial Science and Technological Innovation (ISTI), Room 1250 National Science Foundation, Washington, DC 20550 (202) 357-9666.

Summary of Minutes: May be obtained from the contact person at the above address.

Purpose of Committee: To provide advice and recommendations concerning support of research programs administered in the Division.

Agenda: April 8, 1987; 8:30 a.m.—12:00 noon.

Update on ISTI activities. ISTI administration of the SBIR program and review of new management techniques. The Equipment Donation and Discount program initiatives will be discussed.

April 8, 1987; 1:30 p.m.—5:00 p.m.

Office of Small Business R&D operations will be discussed. The long Range planning for the division will include potential new initiatives and discussion of options.

M. Rebecca Winkler,

Committee Management Officer.

March 16, 1987.

[FR Doc. 87-5936 Filed 3-18-87; 8:45 am]

BILLING CODE 7555-01-M

Advisory Committee for the Mathematical Sciences; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, as amended, the National Science Foundation announces the following meeting:

Name: Advisory Committee for the Mathematical Sciences.

Date & Time: April 6, 1987—10:00 a.m. to 5:30 p.m., April 7, 1987—8:30 a.m. to 3:30 p.m.

Place: Room 540, National Science Foundation, 1800 G Street, NW., Washington, DC 20550.

Type of Meeting: Open—April 6, 1987; 10:00 a.m. to 4:30 p.m., Closed—April 6, 1987; 4:30 p.m. to 5:30 p.m., Open—April 7, 1987; 8:30 a.m. to 3:30 p.m.

Contact Person: Dr. Judith S. Sunley, Deputy Division Director, Division of Mathematical Sciences, Room 339, National Science Foundation, Washington, DC 20550. Telephone (202) 357-9669. Anyone planning to attend this meeting should notify Dr. Sunley no later than April 1, 1987.

Purpose of Committee: To provide advise and recommendations concerning support for research in the mathematical sciences.

Agenda: Monday, April 6, 1987—10:00 a.m. to 4:30 p.m.—Open

Introductory remarks FY 1987 and FY 1988

Budgets Planning Environment

Status of New, Ongoing, and Developing

Programs

Computational mathematics

Research Experiences for Undergraduates

Research Opportunities for Women
(Planning Grant and Career Advancement Options)

Presidential Young Investigators

Graduate Fellowship Programs

Calculus Curriculum Development

Faculty Enhancement

Strategic Planning

Disciplinary base

New opportunities

Education and human resources

Monday, April 6, 1987—4:30 p.m. to 5:30 p.m.—Closed

Discussion of pending proposals with policy implications

Tuesday, April 7, 1987—8:30 a.m. to 3:00 p.m.—Open

Strategic Planning

Possible initiatives for FY 1989

Priorities for the future

Summarizing the committee consensus

Increasing the Effectiveness of the Advisory Committee

Other business

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information, financial data, such as salaries, and personal information concerning individuals associated with the proposal. These matters are within exemptions (4) and (6) of 5 U.S.C. 552(c), Government in the Sunshine Act.

M. Rebecca Winkler,
Committee Management Officer.

March 16, 1987.

[FR Doc. 87-5938 Filed 3-18-87; 8:45 am]

BILLING CODE 7555-01-M

Materials Research Advisory Committee; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the National Science Foundation announces the following meeting:

Name: Materials Research Advisory Committee.

Place: Room 540, National Science Foundation, 1800 G Street, NW., Washington, DC 20550.

Date: Thursday, April 2, and Friday, April 3, 1987.

Time: 8:30 a.m.—5:00 p.m., both days.

Type of Meeting: Part Open (Thursday a.m., Friday), Part Closed (Thursday p.m.).

Contact Person: Dr. Adriaan M. de Graaf, Acting Division Director Division, of Materials Research, Room 408, National Science Foundation, Washington, DC 20550, Telephone: (202) 357-9794.

Summary Minutes: May be obtained from the Contact Person, Dr. Adriaan M. de Graaf, at the above stated address.

Purpose of Committee: To provide advice and recommendations concerning support of materials research.

Agenda *Thursday Morning, April 2, 1987 (Open)*

8:30 a.m. Organizational matters; adoption of minutes.

9:00 a.m. Status Report on Division activities.

10:30 a.m. Briefing on Budgets for FY 1987 and FY 1988.

12:00 Noon Working Lunch.

Thursday Afternoon, April 2, 1987 (Closed)

1:00 p.m. Committee Oversight Review of the Materials Research Laboratories, the Materials Research Groups, the

Instrumentation for Materials Research, and the National Facilities programs.

5:00 p.m. Adjourn.

Friday, April 3, 1987 (Open)

8:30 a.m. Organizational matters.

9:00 a.m. DMR Long Range Plans.

11:00 p.m. Discussion of role and participation of women, minorities and the handicapped in materials research.

12:00 Noon Working Lunch.

1:00 p.m. Plans for future MRAC activities.

2:00 p.m. Meeting with NSF Director.

3:00 p.m. Continuation of LRP and Budget Discussion.

5:00 p.m. Adjourn.

Reasons for Closing: The meeting will consist of a review of grants and declination jackets that contain the names of applicant institution and principal investigators and privileged information contained in declined proposals. The meeting will also include a review of the merit review documentation pertaining to the applications. These matters are within exemptions 4 and 6 of the Government in the Sunshine Act.

M. Rebecca Winkler,
Committee Management Officer.

March 16, 1987.

[FR Doc. 87-5937 Filed 3-18-87; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of Paperwork Reduction Act (44 U.S.C. chapter 35).

1. Type of submission, new, revision, or extension: New.

2. The title of the information, collection: Completeness and Accuracy of Information, 10 CFR.

Part 30, Rules of General Applicability to Domestic Licensing Byproduct Material

Part 40 Domestic Licensing of Source Material

Part 50, Domestic Licensing of Production and Utilization Facilities

Part 40, Domestic Licensing of Production and Utilization Facilities

Part 55, Operators' Licenses

Part 60, Disposal of High-level Radioactive Wastes in Geologic Repositories

Part 61, Licensing Requirements for Land Disposal of Radioactive Waste

Part 70, Domestic Licensing of Special Nuclear Material

Part 71, Packaging and Transportation of Radioactive Material

Part 72, Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation

Part 110, Export and Import of Nuclear Equipment and Material

Part 150, Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under section 274

3. The form number if applicable: Not applicable.

4. How often the collection is required: At any time an applicant or licensee recognizes that it has information with significant health or safety or common defense or security implications, the information must be reported to the NRC notwithstanding the absence of a specific reporting requirement.

5. Who will be required or asked to report: Applicants for and holders of NRC licenses.

6. An estimate of the number of responses: Out of some 9,600 applicants and licensees, experience indicates that on average one response per applicant/licensee may be expected in a normal year.

7. An estimate of the total number of hours needed to complete the requirement or request: 960 (est.)

8. An indication of whether section 3504(h), Pub. L. 96-511 applies: Applies.

9. Abstract: 10 CFR 30.9(b), 40.9(b), 50.9(b), 55.6(b), 60.8(a)(b), 61.8(a)(b), 70.9(b), 71.6(a)(b), 72.9(a)(b), and 110.7(a)(b) codify a general requirement to report to the NRC information with significant health or safety or common defense or security implications, notwithstanding the absence of a specific reporting requirement. Section 150.20(b) codifies the same reporting requirement for an Agreement State licensee who is operating within the NRC's jurisdiction under a general license granted by § 150.20.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 1717 H Street NW., Washington, DC 20555.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 492-8132.

Dated at Bethesda, Maryland, this 4th day of March, 1987.

For the Nuclear Regulatory Commission.

Patricia G. Norry,

Director, Office of Administration

[FR Doc. 87-5985 Filed 3-18-87; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-313; et al.]

Receipt of Petition for Director's Decision; Arkansas Power & Light Co.; Arkansas Nuclear One Unit No. 1 et al.

Docket No. 50-313—Arkansas Power & Light Company, Arkansas Nuclear One, Unit No. 1.

Docket No. 50-348—Toledo Edison Company, et al., Davis-Besse Nuclear Station, Unit No. 1.

Docket No. 50-312—Sacramento Municipal Utility District, Rancho Seco Nuclear Generating Station.

Dockets Nos. 50-438 and 50-439—Tennessee Valley Authority, Bellefonte Nuclear Plant, Units Nos. 1 and 2.

Docket No. 50-302—Florida Power Corporation, et al., Crystal River Unit 3 Nuclear Generating Plant.

Dockets Nos. 50-269, 50-270 and 50-287—Duke Power Company, Oconee Nuclear Station, Units Nos. 1, 2 and 3.

Docket No. 50-289—GPU Nuclear Corporation, et al., Three Mile Island Nuclear Station, Unit No. 1.

The Nuclear Regulatory Commission (NRC) hereby gives notice that, by petition dated February 10, 1987, the Union of Concerned Scientists (UCS)¹ requested the NRC (1) to suspend immediately the operating licenses and construction permits of all utilities (utilities) operating or building nuclear power reactors designed by the Babcock & Wilcox Company (B&W); (2) to require the utilities to modify their B&W designed nuclear generating facilities in order to correct certain alleged safety deficiencies; (3) to hold public hearings on the sufficiency of modifications required in (2) to correct the alleged deficiencies at each plant involved; and, (4) to revoke the operating license or

¹ A number of groups joined in submitting this petition to the Nuclear Regulatory Commission including, as well as the Union of Concerned Scientists, The Arkansas Alliance, Citizens for Land & Water Use, Inc., Concerned Citizens of Ashtabula County, Concerned Citizens of Geauga County, Concerned Citizens of Lake County, Cuyahoga County Concerned Citizens, Frank D. Davis, Ed Deaton, Stan Diorio, Environmental Congress of Arkansas, Fayetteville Peace & Justice Center, Nancy Haller, M.D., Newton County Health Officer, Norman P. Hetrick, Vice-Chairman, Dauphin County Board of Commissioners, Kiski Valley Coalition to Save Our Children, Maryland Nuclear Safety Coalition, Native Americans for a Clean Environment, Northern Ohio Citizens Against Perry & Davis-Besse, People's Action for a Safe Environment, People Against Nuclear Energy, Louis D. Putney, Sacramentoans for Safe Energy, Save Our State From Radioactive Waste, Susquehanna Valley Alliance, Laszlo Tratzkovich, Shelley Tratzkovich, the Western Reserve Alliance, the Coalition for a Nuclear Free Great Lakes, Senator Linda Furney, Ed Green, Timothy F. Hagan, Commissioner, County of Cuyahoga, Larry J. Hochendorfer, Commissioner, Dauphin County Board of Commissioners, Three Mile Island Alert, Toledo Coalition for Safe Energy, Honorable Peter C. Wambach, Jean White, Ozark Organic Growers Association, and Jay Westbrook, Councilman, City of Cleveland. The petitioners will be referred to collectively as the "UCS."

construction permit of any utility that does not meet the proposed requirements that emerge from (3). The UCS' requests concern Arkansas Nuclear One, Unit No. 1, Crystal River Unit 3 Nuclear Generating Plant, Davis-Besse Nuclear Power Station, Unit No. 1, Oconee Nuclear Station, Units Nos. 1, 2, and 3, Rancho Seco Nuclear Generating Station, Three Mile Island Nuclear Station, Unit No. 1, and Bellefonte Nuclear Plant, Units Nos. 1 and 2.

The UCS' Petition alleges a variety of design deficiencies in nuclear power plants designed by B&W. Those alleged design deficiencies form the bases for UCS' requests.

The NRC will treat the petition pursuant to 10 CFR 2.206 (1986) of the Commission's regulations and, accordingly, will take appropriate action on its requests within a reasonable time. A copy of the petition is available for inspection in the Commission's Public Document Room, 1717 H Street NW., Washington, DC, 20555, and in the following Local Public Document Rooms:

Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Crystal River Public Library, 668 N.W. First Avenue, Crystal River, Florida 32629.

Sacramento City-County Library, 828 I Street, Sacramento, California 95813.

Government Publications Section, State Library of Pennsylvania, Education Building, Commonwealth and Walnut Streets, Harrisburg, Pennsylvania 17126.

University of Toledo Library, Documents Department, 2801 Bancroft Avenue, Toledo, Ohio 43606.

Oconee County Library, 501 West Southbroad Street, Wahalla, South Carolina 29691.

Scottsboro Public Library, 1002 South Broad Street, Scottsboro, Alabama 35768.

Dated at Bethesda, Maryland, this 13th day of March 1987.

For the Nuclear Regulatory Commission.
Frank J. Miraglia,

Acting Director, Office of Nuclear Reactor Regulation.

[FR Doc. 87-5987 Filed 3-18-87; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 70-364; License No. SNM-414; DD-87-05]

Babcock & Wilcox; Issuance of Director's Decision

Notice is hereby given that the Director, Office of Nuclear Material Safety and Safeguards, has taken action with regard to Petitioners for action under 10 CFR 2.206 received from Ms. Frances Munko and Mrs. Mildred Chelko, dated July 31, 1986, and August 1, 1986, respectively, with respect to the

Babcock & Wilcox Parks Township facility. The Petitioners request that a proceeding be instituted to revoke the license for the facility and to require that the site be cleaned up. In addition, Ms. Chelko requests that action be taken to require that any other site that contains material or waste from its previous activities and licenses be cleaned up.

The Director of the Office of Nuclear Material Safety and Safeguards has determined to deny the Petitions. The reasons for this denial are explained in the "Director's Decision under 10 CFR 2.206," (DD-87-05) which is available for public inspection in the Commission's Public Document Room, 1717 H Street, NW., Washington, DC 20555. A copy of this decision will be filed with the Secretary for the Commission's review in accordance with 10 CFR 2.206(c) of the Commission's regulations. As provided by this regulation, the decision will constitute the final action of the Commission 25 days after the date of issuance of the decision unless the Commission on its own motion institutes a review of the decision within that time.

Dated at Silver Spring, Maryland, this 12th day of March 1987.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Director, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 87-5988 Filed 3-18-87; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-316]

Indiana and Michigan Electric Co.; Consideration of Issuance of Amendment to Facility Operating License and Opportunity for Prior Hearing; Indiana and Michigan Electric Company

The United States Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operation License No. DPR-74 issued to the Indiana and Michigan Electric Company (the licensee), for operation of the Donald C. Cook Nuclear Plant, Unit No. 2 located in Berrien County, Michigan.

The amendment would add a license condition relating to the repair and replacement of the four steam generators in accordance with the licensee's application for amendment dated March 12, 1987 as supplemented by earlier letter dated November 7, 1986.

Prior to issuance of the proposed license amendment, the Commission will have made findings required by the

Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

By April 20, 1987, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Request for a hearing and petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, and designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of

the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

A request for a hearing or a petition for leave to intervene shall be filed with the Secretary of the Commission, United States Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street NW., Washington, DC by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner or representative of the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to B. J. Youngblood: (petitioner's name and telephone number); (date petition was mailed); (plant name); and (publication date and page number of this *Federal Register* notice). A copy of the petition should also be sent to the Office, of General Counsel-Bethesda, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Gerald Charnoff, Esquire, Shaw, Pittman, Potts and Trowbridge, 1800 M Street, NW., Washington, DC 20036, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i) through (v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated March 12, 1987 as supplemented by earlier letter dated November 7, 1986, both of which are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, DC and at the Maude Preston Palenske

Memorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Dated at Bethesda, Maryland, this 13th day of March 1987.

For the Nuclear Regulatory Commission.

B.J. Youngblood,

Director, PWR Project Directorate #4, Division of PWR Licensing-A.

[FR Doc. 87-5989 Filed 3-18-87; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 40-8348]

Minerals Exploration Co.; Final Finding of No Significant Impact Regarding Termination of Source Material License SUA-1223 for the Minerals Exploration Company R&D In Situ Leach Facility Located in Sweetwater County, WY

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of finding of no significant impact.

(1) Proposed Action

The U.S. Nuclear Regulatory Commission (the Commission) is proposing to terminate Source Material License SUA-1223 for the Minerals Exploration Company's A-3 R&D in situ leach facility located in Sweetwater County, Wyoming.

(2) Reasons for the Finding of No Significant Impact

The Commission's Uranium Recovery Field Office has reviewed the Minerals exploration Company's final closure plan and decommissioning activities which were performed in accordance with the requirements of Source Material License SUA-1223. Based on a review of the decommissioning activities, the Commission has determined that no significant environmental impact has resulted.

The following statements support the finding of no significant impact and summarize the decommissioning activities:

(a) Two test patterns were utilized in the A-3 R&D in situ leach project. Test pattern A was operated for eight days beginning on August 2, 1976 using an ammonium bicarbonate lixiviant. After a ten day pump out, aqueous carbonic acid was used with hydrogen peroxide or oxygen as the oxidant. Injection/production terminated on March 23, 1978. Restoration of Test Pattern A was completed in September 1978 using a ground-water sweep. Post restoration stability monitoring continued through 1984. The Commission accepted the restoration on April 28, 1986.

Test Pattern B was operated from October 15, 1976, to March 23, 1978, utilizing aqueous carbonic acid. Restoration was completed in September 1978 by performing a ground-water sweep. Post restoration stability monitoring continued through 1984. The Commission accepted the restoration on April 28, 1986.

(b) Well field abandonment was performed in accordance with the requirements of the Wyoming State Engineer's Office. Wells were filled with bentonite or drilling mud, followed by dry soil near the top. Each well casing was cut two feet below the ground surface and the tops were capped. The wellfield area was cleaned and later backfilled.

All process tanks, columns, pipes and associated equipment were removed and disposed of at a nearby licensed tailings impoundment. Area gamma surveys indicated contaminated soil which was subsequently removed and disposed in a licensed tailings impoundment.

Soil samples were collected to a 15 centimeter depth and from 15 to 30 centimeters deep from each former well pattern site, the discharge channel, and the evaporation area. Radium-226 concentrations did not exceed the limits specified in 10 CFR Part 40, Appendix A.

(c) Final decontamination tasks were completed in July of 1986. No structures remain on site; all were removed prior to the performance by the license of final gamma exposure rate measurements and soil sampling. Independent verification of site cleanup was performed by the Commission on August 12, 1986. The Commission confirmed that the residual soil Radium-226 concentration did not exceed the limits specified in 10 CFR Part 40, Appendix A.

(d) Environmental monitoring for airborne radionuclides and for direct gamma radiation were performed during operation of the R&D facility. The monitoring results indicated that radionuclide concentrations were well below the respective maximum permissible concentrations for unrestricted areas, and the direct gamma exposure rates were within the range of normal background for the area.

Accordingly, the Commission's Uranium Recovery Field Office has determined that the Decommissioning activities did not have a significant effect on the quality of the human environment. This determination is based on the fact that decontamination to within regulatory limits has been achieved at the licensed site.

In accordance with 10 CFR 51.33(a), the Director, Uranium Recovery Field

Office, made the determination to issue a Draft Finding of No Significant Impact and to accept comments on the draft finding for a period of 30 days after issuance in the *Federal Register*. A Draft Finding of No Significant Impact was published on February 18, 1987 and no comments were received.

In accordance with 10 CFR 51.32, the Director, Uranium Recovery Field Office, made the determination to issue a Final of No Significant Impact. This finding, together with the decommissioning activity documentation, is available for public inspection and copying at the Commission's Uranium Recovery Field Office at 730 Simms Street, Golden, Colorado, and at the Commission's Public Document Room 1717 at H Street NW, Washington, DC.

Dated at Denver, Colorado, this 12th day of March, 1987.

For the Nuclear Regulatory Commission.

Harry J. Pettengill,

Chief, Licensing Branch 2, Uranium Recovery Field Office, Region IV.

[FR Doc. 87-5986 Filed 3-18-87; 8:45 am]

BILLING CODE 7590-01-M

Advisory Committee on Reactor Safeguards Subcommittee on Reliability Assurance Meeting

The ACRS Subcommittee on Reliability Assurance will hold a meeting on April 8, 1987, Room 1046, 1717 H Street NW., Washington, DC.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, April 8, 1987—8:30 a.m. until the conclusion of business

The Subcommittee will review current industry and staff efforts relating to valve reliability.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the ACRS staff member named below as far in advance as is practicable so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be

considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Mr. Richard Major (telephone 202/634-1414) between 8:15 a.m. and 5:00 p.m. Persons planning to attend this meeting are urged to contact the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., which may have occurred.

Dated: March 16, 1987.

Morton W. Libarkin,

Assistant Executive Director for Project Review.

[FR Doc. 87-5969 Filed 3-18-87; 8:45 am]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-24187; File No. SR-BSE-87-1]

Self-Regulatory Organizations; Proposed Rule Change by Boston Stock Exchange, Inc. Relating to Amendments to Chapter XV of the Boston Stock Exchange Rules

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on January 30, 1987 the Boston Stock Exchange, Incorporated ("BSE") filed with the Securities and Exchange Commission the proposed changes as described in items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement on the Terms of Substance of the Proposed Rule Change

The proposed rules establish the Exchange's BEACON System.¹

¹ The text of the proposed rules that will accommodate BEACON was submitted with the filing at Exhibit A. A copy of Exhibit A is available from the Commission at the address noted in Section IV below and at the BSE.

BEACON is an acronym for Boston Exchange Automated Communications and Order-routing Network. BEACON will provide an automated communication, order routing and execution system for use by Exchange member organizations and foreign exchanges with which a linkage has been approved by the Securities and Exchange Commission. BEACON will also automate many regulatory and management reporting functions.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements governing the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose and Statutory Basis for, the Proposed Rule Change

(a). The purpose of the proposed rules is to establish the Exchange's BEACON system. BEACON will provide an automated communication, order routing and execution system for use by Exchange member organizations and with any foreign exchange with which a linkage has been approved by the Securities and Exchange Commission. BEACON will also automate many regulatory and management reporting functions.

(b) The basis under the Act for the proposed Rule change is section 6(b)(5) in the BEACON will facilitate transactions in securities traded on the BSE.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed amendment imposes any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve such proposed change, or
- (B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by April 9, 1987.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: March 6, 1987.

Shirley E. Hollis,
Assistant Secretary.

[FR Doc. 87-5944 Filed 3-18-87; 8:45 am]
BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Midwest Stock Exchange, Inc.

March 12, 1987.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the

Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following stocks:

Multimarket Income Trust
Class A Common Stock, \$0.01 Par Value
(File No. 7-9782)
Fruit of the Loom, Inc.
Common Stock, \$0.01 Par Value (File No. 7-9783)
Templeton Emerging Market Fund, Inc.
Common Stock, No Par Value (File No. 7-9784)
Shaklee Corporation (Delaware)
Common Stock, No Par Value (File No. 7-9785)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before April 2, 1987, written data, views and arguments concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Shirley E. Hollis,
Assistant Secretary.

[FR Doc. 87-5950 Filed 3-18-87; 8:45 am]
BILLING CODE 8010-01-M

[Release No. 34-24199; File No. SR-NYSE-86-38]

Self-Regulatory Organizations; Order Approving Proposed Rule Change of New York Stock Exchange, Inc., Restructuring NYSE Bond Data Fee

I. Description of the Proposal

On December 22, 1986, the New York Stock Exchange, Inc., ("NYSE") filed with the Securities and Exchange Commission a proposed rule change pursuant to section 19(b) of the Securities Exchange Act of 1934 and Rule 19b-4 thereunder. The proposal adopts a fee structure for the NYSE's Bond Data Services identical to the fee structure recently approved for the Network A services under the Consolidated Quotation Plan ("CQ

Plan") and the Consolidated Tape Association Plan ("CTA Plan").¹ The Commission published notice of the proposal on January 30, 1987,² and received no comments.

The cumulative effect of the proposed rule change is to create a single fee that covers the provision of last sale prices and quotations on both NYSE bonds and NYSE-listed stocks.³ In addition to the basic service fee, the fee charge subscribers under the old fee schedules for bond data service was dependent, in part, on whether the subscriber received the information in the form of a ticker or through an interrogation device. Under the restructured fee schedule, the only variable is the total number of ticker or interrogation devices employed.⁴ Under the restructured fee schedule, if subscribers pay any CTA Plan or CQ Plan program classification charges, they are entitled to use both stock and bond data according to the program classification.

The NYSE stated that the fee restructuring is intended to be revenue neutral to the NYSE. A three-year transition period is planned to mitigate the impact on some larger subscribers who have in excess of 100 display devices. As applicable, the dollar impact on these subscribers would be limited during the first year to an amount not to exceed 10% more or 10% less than that paid under the old rates. The excess over 10%, if any, would be spread pro rata over the succeeding 24 months after the end of the first year. For subscribers with fewer than 100 devices, there would be no transition period.

II. Discussion

The Commission believes the NYSE's proposed rule change is consistent with the Act because it provides for an equitable allocation of fees among exchange members and other subscribers.⁵ As not above, the

¹ See Securities Exchange Act Release No. 24130 (February 20, 1987), 52 FR 6413 ("CTA/CQ Release").

² See Securities Exchange Act Release No 24009 (January 20, 1987), 52 FR 3073.

³ Under the old fee schedules, participants paid separately for ticker, last sale and bid-ask quotations. Payment of the fees for any of the services, however, entitled the subscriber to both bond and stock data. The new fee schedule provides for one fee for bond and stock ticker, last sale and bid-ask quotations.

⁴ The proposal also modifies the current structure by eliminating the location charge. Thus, the monthly amount that the subscriber pays would be determined based on the total number of devices without regard to where they are located.

⁵ Section 6(b)(4) of the Act provides that an exchange must have rules that provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities.

Commission recently approved a restructuring of the CTA/CQ fee schedule. The NYSE's current proposal to restructure the bond data service fee essentially incorporates the bond data service fee into the CTA/CQ fee structure. The Commission believes that the proposal is consistent with the Act for the same reasons it found the CTA/CQ plan to be consistent with the Act.⁶ Specifically, the Commission believes that the restructuring of the bond data service fee provides a more simplified rate structure with a single fee for consolidated data that will save receiving firms time, effort and money by eliminating the substantial administrative and recordkeeping tasks required by the current fee structure.

III. Conclusion

The Commission finds the proposed amendments to the NYSE bond data fee schedule to be consistent with the Act and the rules thereunder, particularly section 6(b)(4) of the Act.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change be, and hereby is, approved.⁷

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: March 10, 1987.

Shirley E. Hollis,
Assistant Secretary.

[FR Doc. 87-5945 Filed 3-18-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-24201; SR-NYSE-86-33]

Self-Regulatory Organization; New York Stock Exchange, Inc.; Order Approving Proposed Rule Change

The New York Stock Exchange, Inc. ("NYSE" or "Exchange") submitted on December 9, 1986, copies of a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), and Rule 19b-4 to approve rate increases effecting initial and continuing annual listing fees for companies listed on the Exchange. The NYSE states that those increases have been proposed in order to offset, in part, the increased costs of supplying services provided by the Exchange. These costs include manpower, systems and utilities associated with providing

⁶ See Release No. 24130, *supra* note 1.

⁷ The Commission also is approving the NYSE's request to have the bond data service fee changes become effective as of the date on which the CTA/CQ Network A fee restructuring became effective. The Commission approved the CTA/CQ fee changes on February 20, 1987. See note 1, *supra*.

market place services. These fees were last increased in January 1985.¹

Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by issuance of a Commission release (Securities Exchange Act Release No. 24004, January 16, 1987) and by publication in the *Federal Register* (52 FR 2914, January 28, 1987). No comments were received with respect to the proposed rule change.

The Commission has carefully reviewed the proposed fee increases and finds them to be both moderate and reasonably related to the increased costs cited by the Exchange in processing, and maintaining listings, as required by section 6(b)(4) of the Act.²

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of Section 6 and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: March 10, 1987.

Shirley E. Hollis,
Assistant Secretary.

[FR Doc. 87-5946 Filed 3-18-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-2419; File No. SR-PSE-86-35]

Self-Regulatory Organizations; The Pacific Stock Exchange Inc.; Notice of Filing and Order Granting Accelerated Approval To Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on January 7, 1987, the Pacific Stock Exchange Incorporated filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization.¹ The

¹ Securities Exchange Act Release No. 21635, January 7, 1985, 50 FR 1684.

² E.g., increasing the original listing charge per company from \$31,700 to \$33,200 and raising the annual fee for continued listing of issuers with zero to two million shares from \$1,270 to \$1,320.

³ The Exchange also submitted to the Commission a letter clarifying the purpose of the proposed rule change. Letter from Stacey Suduth Schwartz,

Continued

Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Pacific Stock Exchange Incorporated proposes to amend Options Floor Procedure Advice ("OFPA") B-12 to include all series which are at-the-money, and just-in and just-out of the money, rather than solely the near term, at-the-money series. OFPA B-12 provides that trading crowds should guarantee a depth of ten contracts at the best bid and/or offer when a market at the time such best bid and/or offer is vocalized. In addition, the Exchange proposes to waive the provisions of OFPA B-12 when fast market conditions are declared.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B) and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for the Proposed Rule Change

The purpose of the proposed rule change is to increase the liquidity in the more popular option series for the benefit of public participation. Previously, when first adopting OFPA B-12, the PSE singled out the near term options with strike prices nearest the current price of the underlying security for this provision. Historically, these series have attracted the most attention and the PSE's establishment of OFPA B-12 was designed to ensure adequate liquidity for the order size most associated with such public interest. The Exchange believes the implementation of OFPA B-12 has been a positive improvement to the market place. At this time the PSE feels the need to expand this provision to include all series which are at-the-money and just-in and just out-of the money at the time a request for a market is made.

Compliance Investigator, The Pacific Stock Exchange, to Mary Revell, Attorney, Division of Market Regulation, dated February 10, 1987.

A guarantee of ten contract liquidity is geared to eliminating partially-filled retail orders which tend to boost commission costs for retail customers. By ensuring ten contract liquidity, most public orders should be filled in their entirety. This should reduce the overall transaction costs for public customers of the Exchange. The PSE may in the future expand such liquidity requirements to additional options series.

The purpose for providing a waiver of the requirement for a depth of ten contracts in fast market conditions was described in the Exchange's clarifying letter to the Commission. The Exchange defined a fast market as one where there are no "firm" bids or offers. Since the Exchange does not hold its members liable for bids and offers in fast markets it, therefore, could not compel its members to provide a depth of ten contracts. Accordingly, when fast market conditions are declared, OFPA B-12 may be waived with the approval of two Floor Officials.

The PSE believes that the proposed rule change is specifically in keeping with Section 6 of the Act because it will facilitate transactions in securities and protect investors and the public interest. The whole thrust of the PSE's proposals to facilitate the completion of customer orders.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change imposes no burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Comments on PSE's previous rule filing to establish OFPA B-12 (SR-PSE-86-16) were solicited in Release No. 34-23512 dated August 6, 1986 and none were received. Comments were neither solicited nor received on the proposed rule filing.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange requests that the proposed rule change be given accelerated effectiveness pursuant to section 19(b)(2) of the Act because the Exchange states that, in practice, specialists on the American Stock Exchange have voluntarily committed to a system of "guaranteed markets" similar to this proposal. The Exchange states that the rule change is in the public interest and is designed to better serve that interest. In addition, the Exchange states that the proposed rule change is merely an extension of the

recently approved Exchange rule filing SR-PSE-86-18.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and in particular, the requirements of section 6 and the rules and regulations thereunder, in that it is intended to add depth and liquidity to more options series.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof because the rule change is an extension of Exchange rule filing SR-PSE-86-16 which was approved by the Commission in Release No. 34-23775 dated November 4, 1986. That rule change imposed a requirement that trading crowds would guarantee a depth of ten contracts at the best bid and/or offer when a market at the time such best bid and/or offer is vocalized. The Exchange's proposed rule change will help to promote just and equitable principles of trade because it will facilitate transactions in securities, and enhance the efficiency of executions of the PSE options floor by adding more depth to specified options series.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned, self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by April 9, 1987.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change is approved. For the Commission, by the Division of

Market Regulation, pursuant to delegated authority.

Dated: March 9, 1987.

Shirley E. Hollis,
Assistant Secretary.

[FR Doc. 87-5947 Filed 3-18-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-24205; File No. PHLX 86-40]

**Self-Regulatory Organizations;
Proposed Rule Change by the
Philadelphia Stock Exchange, Inc.
Relating to Escrow Receipts**

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on December 1, 1986 the Philadelphia Stock Exchange, Inc. filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Proposed Rule Change

The Philadelphia Stock Exchange ("PHLX") proposes to amend Rule 722(c)(2)(G) as follows. (Brackets indicate deletions and italics indicates additions.)

No margin need be required in respect of a put or call option contract issued, guaranteed or carried "short" for a customer's account when, (i) in the case of a call option contract *on an equity security*, the customer has delivered to the member organization carrying [such] the customer's account an "escrow receipt" meeting the requirements of Rule 610 of the Options Clearing Corporation [or an option guarantee letter in a form satisfactory to and issued by a custodian approved by the Exchange] which certifies that the custodian issuing [such] the "escrow receipt" [or option guarantee letter] holds for the account of the customer the underlying security (or a security immediately convertible into the underlying security without payment of cash) [or the underlying foreign currency, as the case may be, represented by such call option contract] and that [such] the underlying security [or underlying foreign currency] will be delivered to the member organization (or where applicable, to the order to the Options Clearing Corporation) against payment of the aggregate exercise price of [such] the call

option contract; (ii) *in the case of a call option contract on a foreign currency, the customer has delivered to the member organization carrying the customer's account an "escrow receipt" meeting the requirements of Rule 610 of the Options Clearing Corporation which certifies that the custodian issuing the "escrow receipt" holds for the account of the customer (1) The number of units of the underlying foreign currency represented by the call; (2) debt securities, issued by the government issuing the underlying foreign currency or investment—grade corporate debt securities, calling for payment of principal and interest in the underlying foreign currency, provided that the debt securities have an aggregate market value, computed as of the close of business on the day the call option contract is written, of not less than 120% of the amount of the underlying foreign currency represented by the call; or (3) a combination thereof; and that the requisite number of units of the underlying currency will be delivered to the member organization (or, where applicable, to the order of the Options Clearing Corporation) against payment of the aggregate exercise price of the call option contract; or (iii) in the case of a call option contract on a foreign currency, the customer has delivered to the bank account designated by the member organization carrying [such] the customer's account the number of units of the underlying foreign currency represented by [such] the call option contract; (iv) in the case of a call option contract on a market index stock group, [the letter of guarantee must] an option guarantee letter, in a form satisfactory to, and issued by a custodian approved by, the Exchange, which guarantee letter certifies that the guarantor holds for the account of the customer as security for the letter: (1) Cash, (2) cash equivalents, (3) one or more qualified securities, or (4) a combination thereof, that such deposit has an aggregate market value, computed as of the close of business on the day the call option contract is written, of not less than 100% of the aggregate current index value as computed at the same time and that the guarantor will promptly pay the member organization the exercise settlement amount in the even the account is assigned an exercise notice. A qualified security means: (1) an equity security, other than a warrant, right or option, that is traded on any national securities exchange and substantially meets the original listing requirements of the American Stock Exchange for such security, or (2) any security, other than a warrant, listed in the current list of Over-The-Counter Margin Stocks as*

published by the Board of Governors of the Federal Reserve System; (v) in the case of a put option contract (including a put on a foreign currency or on a market index stock group), the customer has delivered to the member organization carrying [such] the customer's account an option guarantee letter in form satisfactory to, and issued by a custodian approved by, the Exchange, which certifies that the guarantor holds for the account of the customer as security for the letter, cash or cash equivalents which have an aggregate market value, computed as at the close of business on the day the put option contract is written, of not less than 100% of the aggregate exercise price of the put option contact and that the guarantor will promptly pay the member organization the exercise settlement amount (in the case of a put option contract on a market index stock group) or the aggregate exercise price (in the case of any other put option contract) in the event the account is assigned an exercise notice. Cash equivalents shall mean those instruments referred to in § 220.8(a)(3)(ii) of Regulation T of the Board of Governors of the Federal Reserve System. Investment—grade corporate debt securities are securities which are not traded flat or in default as to principal or interest and which are rated in one of the four highest rating categories by at least two recognized statistical rating organizations (see R. 15c3-1(c)(2) (vi)(F) and #I.B.2. of the instructions to Form 5-3.).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statements of the Purpose of, and Statutory Basis for the Proposed Rule Change

The proposed rule change, which is in response to inquiries from member firms, would establish a foreign currency option ("FCO") escrow receipt which could be utilized to cover short call options positions. It is designed to

permit foreign currency options customers to use foreign currency or foreign currency denominated securities as "cover" to satisfy Exchange margin requirements.

Under the proposal, the issuer of the escrow receipt would be obligated to deliver the amount of the underlying currency represented by the call options. To support the bank's assurance of performance, the customer would have to deposit with the bank either: (i) The amount of underlying currency represented by the call; or (ii) government-issued or investment-grade corporate debt securities denominated in the foreign currency equal in value, at the time the escrow receipt is issued, to 120% of the amount of the underlying foreign currency. The escrow receipt would operate as "cover" for short options positions and thus could be posted by the customer in lieu of margin.

The 20% haircut for foreign-currency denominated debt securities has been proposed because of the fact that bonds, even if denominated in the foreign currency, can deviate in value from the cash market in the currency because of changes in interest rates. While the amount of this potential deviation varies with the length to maturity of the debt securities, the exchange is initially utilizing a single, very conservative haircut for simplicity's sake and to assure the promptest possible consideration by the Securities and Exchange Commission and the Federal Reserve Board. In addition, PHLX would not anticipate, at least at first, the potential users would seek to write currency options against the value of an entire debt security position. PHLX would expect, however, as the program becomes more firmly established, to seek to develop a more refined haircut schedule if interest warranted it.

The proposed rule change has been approved by the Board of Directors of the Options Clearing Corporation ("OCC") for filing with the Securities and Exchange Commission.

Securities and Exchange Commission approval of it would mark a substantial improvement in the treatment of FCO cover under OCC rules. For example, the Exchange currently permits customers to furnish their brokers as cover bank-issued option guarantee letters evidencing that the customer has on deposit the requisite amount of the underlying foreign currency. These guarantee letters, however, cannot now be shipped upstream to satisfy the broker's OCC margin obligations.

The proposal is consistent with, albeit an extension from, traditional concepts of cover. Historically, short call options positions have been deemed "covered"

only if the underlying stocks, or securities convertible into those stocks, were deposited against those calls. With the advent of stock index options, it was recognized that the concept of cover would have to be expanded if covered writing were to be feasible. In particular, it was recognized that it was not practicable to require an investor to deposit all 20-1700 stocks in an underlying index and that, as cash settlement instruments, stock index options did not warrant such deposits. Hence, it was determined that, so long as customers were not permitted to obtain leverage and non-performance risks were avoided, traditional concepts of cover would be expanded to accommodate index options. Those requirements were satisfied by development of an index option escrow receipt collateralized with either cash, one or more appropriate stocks or a combination thereof equal in value to the aggregate value of the underlying index.

Similar necessity compels an extension of the concept of cover in the currency options context. Consistent with traditional notions of cover, the proposed escrow receipt could be supported by a deposit of the underlying currency. For most international investors, however, it is not practicable or economical to hold on deposit over an extended period of time the actual underlying currency. These investors, however, may have significant investment positions denominated in a foreign currency. While writing call options against such securities would not eliminate interest rate or credit risks, they would reduce a significant risk element, exchange rate exposure. Hence allowing such securities to serve as cover appears a sensible application of traditional concepts of cover in a new context.

Another advantage of the proposal is that it would enable currency options to be written in a cash account. The Exchange's letter of credit program has reduced the cash outlays currency option writers are required to make, but still requires that trading activity occur in a margin account. A number of institutional investors are precluded by regulation, charter or trust agreement from uncovered writing or trading in a margin account.

Finally, by working with OCC, the proposal will enable brokers to use customer escrow receipts to satisfy their clearing firm margin obligations with OCC. The Exchange's current option guarantee letters are seldom utilized, at least in part because firms are reluctant to accept them without being able to forward them to OCC.

The proposed rule change is consistent with section 8(b)(5) of the Securities and Exchange Act of 1934 in that it will facilitate transactions in securities and protect investors and the public interest.

B. Self-Regulatory Organizations Statement on Burden on Competition

The PHLX does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of the publication of this notice in the *Federal Register* or within such longer period: (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- A. By order approve such proposed rule change or
- institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by April 9, 1987.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: March 11, 1987.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 87-5948 Filed 3-18-87; 8:45 am]

BILLING CODE 8010-01-M

**Self-Regulatory Organizations;
Applications for Unlisted Trading
Privileges and of Opportunity for
Hearing; Philadelphia Stock Exchange,
Inc.**

March 12, 1987.

The above named national security exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following securities:

IMO Delaval Inc.

Common Stock, \$1.00 Par Value (File No. 7-9780)

PepsiCo, Inc. (North Carolina)

Capital Stock, \$0.05 Par Value (File No. 7-9781)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before April 2, 1987, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 87-5951 Filed 3-18-87; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. IC-15620; 811-4814]

**Certificate of Deposit Trust, Series 1
(and Subsequent Series); Application
for Deregistration**

March 11, 1987.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the "1940 Act").

Applicant: Certificate of Deposit Trust, Series 1 (and Subsequent Series).

Relevant 1940 Act Section:

Deregistration under section 8(f).

Summary of Application: Application seeks an order declaring that it has ceased to be an investment company.

Filing Date: The application was filed on December 8, 1986.

Hearing or Notification of Hearing: If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this application, or ask to be notified if a hearing is ordered. Any requests must be received by the SEC by 5:30 p.m., on April 6, 1987. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicant with the request, either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit, or, for lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicant, c/o Miller & Schroeder Financial, Inc., 2400 Northwestern Financial Center, 7900 Xerxes Avenue South, Bloomington, Minnesota 55431.

FOR FURTHER INFORMATION CONTACT: Paul J. Heaney, (202) 272-3015, or Special Counsel Karen L. Skidmore, (202) 272-3023, Division of Investment Management.

SUPPLEMENTARY INFORMATION:

Following is a summary of the application; the complete application is available for a fee from either the SEC's Public Reference Branch in person, or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 258-4300).

Applicant's Representations

1. Applicant filed a registration statement on Form N-8B-2 pursuant to section 8(b) of the Act on August 25, 1986, to register under the Act as a unit investment trust. Prior to that date, Applicant privately placed securities of

Applicant's first three series with a total of not more than 100 persons. On August 25, 1986, Applicant also filed a registration statement on Form S-6 for registration of 400 units of Certificate of Deposit Trust, Series 4 ("Series 4") under the Securities Act of 1933 ("1933 Act") (File No. 33-8103). Such registration did not become effective and Applicant did not publicly disseminate a preliminary prospectus and did not make a public offering of these units. Series 4 filed an application pursuant to Rule 477 of Regulation C under the 1933 Act on December 12, 1986 for withdrawal of its registration statement on Form S-6; its registration statement was accordingly withdrawn on December 18, 1986.

2. Applicant consists of three series that are trusts created under the laws of the State of Minnesota with Miller & Schroeder Financial, Inc. acting as depositor and principal underwriter. The assets of these series consists of certificates of deposit maturing in July 1988 in a total principal amount of \$27 million. These series will remain in existence until terminated in accordance with the documents pursuant to which these series were created. The number of holders of the securities of Applicant is 83 and these securities holders own units of Certificate of Deposit Trust, Series 1 through 3.

3. Applicant has never made a public offering of its securities, does not propose to do so, and has no more than 100 holders of its outstanding securities for purposes of section 3(c)(1) of the Act and the rules thereunder, and therefore is excluded from the definition of an investment company.

4. Applicant has not transferred any of its assets to a separate trust within the last 18 months. Applicant is not a party to any litigation or administrative proceedings. Applicant is not now engaged, and does not propose to engage, in any business activities other than continuation of Certificate of Deposit Trust, Series 1 through 3, in accordance with the documents pursuant to which these series were created.

For the Commission, by the Division of Investment Management, under delegated authority.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 87-5952 Filed 3-18-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. IC-15619; 812-6598]

GNA Investors Trust; Application

March 11, 1987.

AGENCY: Securities and Exchange Commission ("SEC").**ACTION:** Notice of Application for Exemption under the Investment Company Act of 1940 (the "1940 Act").*Applicant:* GNA Investors Trust ("Applicant").*Relevant 1940 Act Sections:*

Exemption requested under section 6(c) from the provisions of sections 2(a)(32), 2(a)(35), 22(c) and 22(d) of the 1940 Act and Rule 22c-1 thereunder.

Summary of Application: Applicant seeks an order to permit it to assess a contingent deferred sales charge ("CDSC") on certain redemptions of shares of its U.S. Government Fund (the "Fund") and any subsequently created series; and to permit it to waive or defer the CDSC under the circumstances described in the application.*Filing Date:* The application was filed on January 15, 1987.*Hearing or Notification of Hearing:* If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this application, or ask to be notified if a hearing is ordered. Any requests must be received by the SEC by 5:30 p.m. on April 6, 1987. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicant with the request, either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit, or, for lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the SEC.**ADDRESS:** Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. GNA Investors Trust, Suite 3300, One Union Square, Seattle, WA 98101.**FOR FURTHER INFORMATION CONTACT:** Joyce M. Pickholz, Staff Attorney, (202) 272-3046, or H.R. Hallock, Jr., Special Counsel, (202) 272-3030 (Division of Investment Management).**SUPPLEMENTARY INFORMATION:**

Following is a summary of the application; the complete application is available for a fee from either the SEC's Public Reference Branch in person or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 253-4300).

Applicant's Representations

1. Applicant, an open-end management investment company, is a "series company" whose shares are

offered for sale to the public through broker-dealers pursuant to distribution agreements with GNA Securities, Inc. (the "Distributor"), Applicant's principal underwriter. The Applicant's investment adviser, GNA Capital Management, Inc., and its Distributor are wholly-owned subsidiaries of GNA Corporation which is a subsidiary of Weyerhaeuser Company.

2. Applicant proposes to offer shares of the Fund without the imposition of a front-end sales load and proposes to impose a CDSC upon redemption of those shares by investors, with certain exceptions noted below. The CDSC imposed upon redemption would not, in the aggregate, exceed 5% of the aggregate purchase payments made by the investor. Applicant requests an order that would apply to shares of its one existing series, the Fund, and all shares of beneficial interest of any series that is subsequently created and which are issued and sold with a CDSC on substantially the same basis as shares of the Fund.

3. The CDSC will be imposed if an investor redeems an amount of shares that causes the value of the investor's account with the Fund to fall below the total dollar amount of purchase payments made by the investor during the preceding five years. However, no CDSC will be imposed to the extent that the aggregate net asset value of the shares redeemed does not exceed: (i) The current net asset value of shares purchased more than five years prior to the redemption, plus (ii) the current net asset value of shares purchased through reinvestment of dividends or capital gains distributions, plus (iii) increases in the net asset value of the investor's shares above the total amount of payments for the purchase of shares of the Fund made during the preceding five years.

4. In determining the applicability of a CDSC to each redemption, the amount that represents an increase in the net asset value of the investor's shares above the amount of the total payments for the purchase of shares within the last five years will be redeemed first. In the event the redemption amount exceeds such value, the next portion of the amount redeemed will be the amount which represents the net asset value of the investor's shares purchased more than five years prior to the redemption and/or shares purchased through reinvestment of dividends or distributions. Any portion of the amount redeemed that exceeds those amounts will be subject to a CDSC.

5. When a CDSC is imposed, the amount of the charge will depend on the number of years since the investor made

the purchase payment from which an amount is being redeemed. The CDSC imposed will be 5% during the first year following the purchase and will decrease 1% per year through the fifth year with no charge imposed in the sixth and subsequent years. The amount of the CDSC (if any) is calculated by determining the date on which the purchase payment that is the source of the redemption was made,¹ and applying the appropriate percentage to the amount of the redemption subject to the charge. In determining the rate of any CDSC, it will be assumed that a redemption is made of shares held by the investor for the longest period of time within the applicable five-year period. This will result in any such charge being imposed at the lowest possible rate.

6. The Fund proposes to finance its own distribution expenses pursuant to a distribution plan adopted under Rule 12b-1 under the Act (the "Plan"). Under the proposed Plan, the Fund will pay a fee to the Distributor in connection with the offering of the Fund's shares. These expenses include advertising and promotional costs, sales administration and related sales expenses, including sales commissions, incentive compensation and the costs of printing and distributing prospectuses to prospective investors. The Fund's distribution fee is accrued daily and paid monthly and is calculated at the rate of .85% of its average daily net assets. The Distributor also will receive the proceeds of all unwaived CDSCs imposed upon redemptions. As part of its review of the Plan pursuant to Rule 12b-1, Applicant's board of trustees will consider the use by the Distributor of any CDSCs it receives.

7. The Applicant believes that the imposition of the CDSC is fair and is in the best interest of shareholders of the Fund. The proposed transaction permits shareholders to have the advantage of more investment dollars working for them from the time of their purchase of shares of the Fund than is possible with the traditional front-end load fund. Moreover, because the CDSC applies only to redemptions of amounts representing purchase payments (during the first five years after the payments), it does not apply to increases in the value per share, or to amounts representing reinvestment of distributions. When amounts attributable to purchase

¹ Solely for purposes of determining the number of years from the time of any payment for the purchase of shares, all payments during a month will be aggregated and deemed to have been made on the last day of the month.

payments are redeemed (and thus no longer contribute to the annual distribution charge), it is fair to impose on the withdrawing shareholder a lump-sum payment reflecting approximately the amount of distribution expense that has not been recovered through payments by the Fund. The amount, computation and timing of the CDSC thus are designed to promote fair treatment of all shareholders while permitting the Fund to offer investors the advantage of having purchase payments fully invested on their behalf immediately.

8. The Fund proposes to waive the CDSC on any redemption following the death of a sole shareholder. This waiver of the CDSC applies to a total or partial redemption, but only to redemptions of shares held at the time of the death.

9. The Fund, as disclosed in its prospectus, has reserved the right to involuntarily redeem shareholder accounts which have less than \$500 in the account at the end of any month. It proposes to waive the CDSC on redemption of such accounts which have been involuntarily redeemed.

10. Shares of the Fund may be exchanged for shares of any other subsequent series of the Applicant, or *vice versa*, as long as after the initial exchange the amount in the fund into which the exchange is made is at least equal to \$1,500. No CDSC will be payable upon such an exchange, but a CDSC will be payable upon the redemption of shares of the fund acquired as a result of the exchange. For purposes of calculating the amount of this charge, the initial purchase date will be deemed to be the last day of the month in which the shares of the first fund being exchanged were purchased rather than the date of the exchange. Thus, the CDSC is being deferred until such time as the shareholder ultimately redeems shares of the fund acquired as a result of the exchange.

11. The waiver of the CDSC in the extraordinary circumstances of death of the investor and on involuntary liquidations of shareholders' accounts is justified on basic considerations of fairness. The deferral of the CDSC in connection with the exchange privilege of the Fund and any subsequent series of the Applicant will be fair and equitable to shareholders of the Fund while at the same time giving them desirable flexibility in their financial planning.

For the Commission, by the Division of Investment Management, under delegated authority.

Shirley E. Hollis,
Assistant Secretary.

[FR Doc. 87-5953 Filed 3-18-87; 8:45 am]
BILLING CODE 8010-01-M

[Release No. 35-24340]

Filings Under the Public Utility Holding Company Act of 1935 ("Act")
Nonongahela Power Co. et al.

March 12, 1987.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendment(s) thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by April 6, 1987 to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy of the relevant applicant(s) and/or declarant(s) at the addresses specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Monongahela Power Company, et al.
(70-7300)

Monongahela Power Company ("Monongahela"), 1310 Fairmont Avenue, Fairmont, West Virginia 26554, The Potomac Edison Company ("Potomac"), Downsville Pike, Hagerstown, Maryland 21740, and West Penn Power Company ("West Penn"), 800 Cabin Hill Drive, Greensburg, Pennsylvania 15601, wholly owned electric utility subsidiaries of Allegheny Power System, Inc., a registered holding company, have filed an application-declaration pursuant to sections 6(a),

6(b), and 7 of the Act and Rule 50 thereunder.

Monongahela, Potomac, and West Penn propose to issue and sell, pursuant to the alternative competitive bidding procedures, their first mortgage bonds in the maximum aggregate principal amounts of \$115 million, \$110 million, and \$35 million, respectively. Alternatively, the companies may, by amendment, seek authorization to negotiate the terms and conditions of the bonds. The bonds will be issued in one or more series from time to time not later than December 31, 1987, with maturities of from five to thirty years.

Atlantic Energy, Inc. (70-7323)

Atlantic Energy, Inc. ("Atlantic Energy"), 1199 Black Horse Pike, Pleasantville, New Jersey 08232, has filed an application pursuant to sections 9(a)(2) and 10 of the Act.

Atlantic Energy is a wholly owned, inactive subsidiary of Atlantic City Electric Company ("Atlantic Electric"), a New Jersey corporation engaged in the business of providing electric service to the public throughout southern New Jersey. Atlantic Electric is also the sole owner of Deepwater Operating Company ("Deepwater"), a New Jersey corporation which operates an electric generating station in Salem County, New Jersey. Deepwater is an "electric utility company" within the meaning of section 2(a)(3) of the Act, and Atlantic Electric is a holding company within the meaning of section 2(a)(7)(A). Pursuant to annual filings of exemption statements under Rule 2, Atlantic Electric and its subsidiaries are presently exempt from all the provisions of the Act and rules thereunder, except section 9(a)(2).

Atlantic Energy proposes to acquire all of the outstanding common shares of Atlantic Electric pursuant to an Agreement and Plan of Merger ("Agreement"). Atlantic Energy will organize a subsidiary, X-Atlantic Inc. ("X-Atlantic"), to effect the merger. Under the Agreement, X-Atlantic will be merged into Atlantic Electric, which will be the surviving corporation. At the time such merger becomes effective, (i) all outstanding common shares of Atlantic Electric will be converted into outstanding common shares of Atlantic Energy, (ii) all outstanding common shares of X-Atlantic will be converted into the number of Atlantic Electric common shares outstanding immediately prior to the merger and (iii) all common shares of Atlantic Energy outstanding prior to the merger will be cancelled. As a result of the merger,

all holders of Atlantic Electric common stock will become holders of Atlantic Energy common stock. Atlantic Energy will, in turn, own all the outstanding common stock of Atlantic Electric.

The stated purpose of the merger is to create a corporate structure which allow diversification on a limited into nonutility activities while better insulating the utility ratepayers of Atlantic Electric from the risks associated with such activities. Atlantic Energy has agreed to strict limitations on any diversification. It is stated that the merger will have no effect upon the electric utility business and operations of Atlantic Electric and Deepwater. All preferred stock and debt securities of Atlantic Electric outstanding at the merger will continue as such. The investments of holders of Atlantic Electric common shares will change in form, but not in substance, upon the merger.

Following a public evidentiary hearing, the New Jersey Board of Public Utilities ("BPU") issued an order on January 5, 1987, approving the proposed restructuring and related transactions. The order affirmed that the broad powers to regulate utilities granted by Title 48 of the New Jersey Statutes would enable the BPU to protect the public, Atlantic Electric, and its customers while allowing Atlantic Electric's affiliated enterprises to avail themselves of opportunities in the market place and to contribute to the economic growth of New Jersey.

Atlantic Electric plans to submit the proposed merger for approval at the annual meeting of stockholders scheduled for April 22, 1987. Following the merger, Atlantic Electric will remain a holding company with respect to Deepwater. Atlantic Energy will become a holding company, and Atlantic Electric and Deepwater will become its direct or indirect subsidiaries and affiliates. However, Atlantic Energy anticipates that both Atlantic Electric and itself will continue to meet the requirements for exemption of section 3(a) and/or (2) and Rule 2 thereunder.

Ohio Power Company, et al. (70-7247)

Ohio Power Company ("Ohio Power"), an electric utility subsidiary of American Electric Power Company, Inc., a registered holding company, and Ohio Power's coal-mining subsidiaries, Central Ohio Coal Company, Southern Ohio Coal Company and Windsor Power House Coal Company (together, "Subsidiaries"), 1 Riverside Plaza, Columbus, Ohio 43215, have filed a post-effective amendment to their application-declaration subject to

sections 9(a), 10 and 12(b) of the Act and Rule 45 thereunder.

By order dated June 6, 1986 (HCAR No. 24120), the Subsidiaries were authorized to lease mining equipment with an aggregate acquisition cost not exceeding \$16.5 million from a nonassociated company and Ohio Power was authorized to guarantee the payments of one of the Subsidiaries. Ohio Power and the Subsidiaries now propose a total aggregate acquisition cost not exceeding \$25 million.

Louisiana Power and Light Company (70-7355)

Louisiana Power and Light Company ("Louisiana"), 142 Delaronde Street, New Orleans, Louisiana 70114, a wholly owned subsidiary of Middle South Utilities, Inc., a registered holding company, has filed an application-declaration under sections 6(a), 7, 9(a), 10 and 12(c) of the Act, and Rules 42 and 50 (a)(5) thereunder.

Louisiana proposes to issue and sell an aggregate principal amount not to exceed \$200,000,000 of first mortgage bonds in one or more series from time to time through December 31, 1988, and to issue and sell an aggregate principal amount not exceed \$100,000,000 of preferred stock, \$25 par value, or \$100 par value, in or or more series, from time to time through December 31, 1988.

Louisiana proposes to use the net proceeds from the sales for the acquisition, in whole or in part, through tender offers, of one or more series of the company's outstanding first mortgage bonds, for the redemption, in whole or in part, of one or more series of the company's high dividend rate preferred stock, or for the repayment of short-term borrowings incurred for that purpose, and for other corporate purposes.

Louisiana requests an exception from the competitive bidding requirements of Rule 50 pursuant to subparagraph (a)(5) so that Louisiana can negotiate the terms of the issuance and the sale of the new first mortgage bonds and the new preferred stock. Louisiana may proceed to negotiate the terms of the proposed first mortgage bonds and preferred stock.

System Energy Resources, Inc. (70-7356)

System Energy Resources, Inc. ("SERI"), P.O. Box 23070, Jackson, Mississippi 39225-3070, a subsidiary of Middle South Utilities, Inc., a registered holding company, has filed an application pursuant to sections 9(a) and 10 of the Act.

SERI has, pursuant to prior Commission authorization, entered into a Fuel Lease, dated as of October 17,

1979, as heretofore amended ("Lease"), with Port Gibson Energy, Inc., ("Port Gibson") under which SERI leases from Port Gibson the nuclear fuel, including facilities incident to its use ("Nuclear Fuel"), used to satisfy a portion of the fuel requirements of Unit No. 1 at SERI's Grand Nuclear Generating Station ("Grand Gulf 1") (HCAR No. 22979; June 17, 1983).

Under the terms of the Lease, Port Gibson makes payments to suppliers, processors and manufacturers, necessary to carry out the terms of SERI's contracts for Nuclear Fuel for Grand Gulf 1 or SERI makes such payments and is reimbursed by Port Gibson. The current maximum obligation of Port Gibson to make payments for Nuclear Fuel is \$174 million at any one time outstanding; however, up to \$175 million of Nuclear Fuel may be paid for at Port Gibson's option. It is proposed that these amounts be increased to \$199 and \$200 million, respectively.

Port Gibson has financed these obligations under a Credit Agreement, dated as of October 17, 1979. Port Gibson, has advised SERI that it is willing to enter into a new Credit Agreement ("Credit Agreement") with Union Bank of Switzerland ("UBS"), certain other banks ("Banks"), and UBS, as agent for the Banks, to provide for the increased funding. Both the Lease and the Credit Agreement will be effective through June 30, 1990, optionally renewable through June 30, 1992. The Banks will receive an assignment of rents and certain other obligations under the Fuel Lease, and a security interest in the Nuclear Fuel owned by Port Gibson and leased to SERI under a Security Agreement.

SERI may terminate the Lease at any time. Port Gibson may terminate the Lease under certain circumstances. The Lease requires that SERI consent to Port Gibson's entry into the Credit Agreement.

Middle South Utilities, Inc. (70-7358)

Middle South Utilities, Inc. ("MSU"), 225 Baronne Street, New Orleans, Louisiana 70112, a registered holding company, has filed a declaration with this Commission pursuant to Section 12(b) of the Act and Rule 45 thereunder.

Pursuant to prior Commission authorization, MSU entered into a guaranty, dated as of October 17, 1979, as heretofore amended ("Guaranty"), with Port Gibson Energy, Inc. ("Port Gibson"), under which it unconditionally guaranteed the performance of the obligations of System Energy Resources, Inc. ("SERI")

with respect to a lease of nuclear fuel, including facilities incident to its use ("Nuclear Fuel"), used to satisfy a portion of the fuel requirements of Unit No. 1 at SERI's Grand Gulf Nuclear Generating Station ("Grand Gulf 1"), under the terms of a Fuel Lease ("Fuel Lease"), dated as of October 17, 1979, as heretofore amended, between SERI and Port Gibson (HCAR No. 22142, July 27, 1981).

The maximum commitment of Port Gibson to make payments in respect of Nuclear Fuel is currently \$174 million at any one time outstanding; however, up to \$175 million of Nuclear Fuel may be paid for at Port Gibson's option. It is now proposed by SERI and Port Gibson in a companion filing (File No. 70-7356) to increase such commitments to \$199 and \$200 million respectively. MSU has been advised that Port Gibson proposes to enter into a new Credit Agreement ("Credit Agreement") with Union Bank of Switzerland, ("UBS") and certain other banks ("Banks") to provide for the increased funding. Both the Fuel Lease and the Credit Agreement will be effective through June 30, 1990, optionally renewable through June 30, 1992. The Banks will receive an assignment of Port Gibson's rights under the Guaranty pursuant to an Assignment Agreement.

MSU proposes to enter into an Amended and Restated Guaranty with Port Gibson and to acknowledge notice and consent to the assignment of Port Gibson's rights under MSU's Guaranty to UBS as agent for the Banks.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Shirley E. Hollis,
Assistant Secretary.

[FR Doc. 87-5954 Filed 3-18-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 35-24341]

Filings Under the Public Utility Holding Company Act of 1935 ("Act"); Northeast Utilities

March 12, 1987

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendment(s) thereto is/are available for public inspection through

the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by April 6, 1987, to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the addresses specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Northeast Utilities (70-7357)

Notice of Amendment of Declaration of Trust Order Authorizing Solicitation of Proxies

Northeast Utilities ("NU"), 174 Brush Hill Avenue, West Springfield, Massachusetts, 01089, a registered holding company, has filed a declaration pursuant to sections 6(a)(2), 7(e) and 12(e) of the Act, and Rules 62 and 65 thereunder.

NU proposes to amend its declaration and trust to increase the authorized number of common shares from 130,000,000 to 225,000,000. As of December 31, 1986, 108,669,106 common shares were issued and outstanding. NU also proposes to amend its declaration of trust to limit the liability of its trustees, officers, agents and other elected or appointed representatives, as permitted by Massachusetts law.

Approval of the amendments requires the affirmative vote of the holders of a majority of NU's outstanding common stock. NU therefore proposes to solicit proxies for approval of the amendments at the annual meeting of stockholders to be held on May 19, 1987. NU has filed a draft of descriptive material to be included in the proxy statement and requests that the effectiveness of its declaration with respect to the solicitation of proxies be accelerated as provided in Rule 62.

It appearing to the Commission that NU's declaration regarding the proposed solicitation of proxies should be permitted to become effective forthwith pursuant to Rule 62:

It Is Ordered, that the declaration regarding the proposed solicitation of proxies be, and it hereby is, permitted to

become effective forthwith, pursuant to Rule 62, and subject to the terms and conditions prescribed in Rule 24 under the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Shirley E. Hollis,
Assistant Secretary.

[FR Doc. 87-5955 Filed 3-18-87; 8:45 am]

BILLING CODE 8010-01-M

[Ref. No. IC-15616; 811-4126]

Viking Tax-Free Fund, Inc.; Deregistration

March 11, 1987.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 (the "1940 Act").

Applicant: Viking Tax-Free Fund, Inc. ("Applicant").

Relevant 1940 Act Section: Section 8(f) and Rule 8f-1 thereunder.

Summary of Application: Applicant seeks an order declaring that it has ceased to be an investment company.

Filing Date: The application on Form N-8F was filed on January 21, 1986.

Hearing or Notification of Hearing: If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this application, or ask to be notified if a hearing is ordered. Any requests must be received by the SEC by 5:30 p.m., on April 3, 1987. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicant with the request, either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit or, for lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicant, c/o Morgan, Lewis & Bockius, 2000 One Logan Square, Philadelphia, PA 19103, Attention: Robert A. Scott.

FOR FURTHER INFORMATION CONTACT: Victor R. Siclari, Staff Attorney (202) 272-3037 or Brion R. Thompson, Special Counsel (202) 272-3016 (Division of Investment Management).

SUPPLEMENTARY INFORMATION:

Following is a summary of the application; the complete application on Form N-8F is available for a fee from either the SEC's Public Reference

Branch in person or the SEC's commercial copier who may be contacted at (800) 231-3282 (in Maryland (301) 258-4300).

Applicant's Representations

1. On October 12, 1984, Applicant, a Maryland corporation, filed a registration statement on Form N-1A, thereby registering under the 1940 Act as open-end, diversified, management investment company. Applicant never made a public offering of its securities and is not a party to any litigation or administrative proceedings. The only debts or liabilities of Applicant which remain outstanding are debts to its sponsor, Fairfield Group, Inc., that were incurred in connection with Applicant's organization. Applicant has no shareholders and is not now engaged, nor does it propose to engage, in any business activities other than those necessary for the winding-up of its affairs.

For the Commission, by the Division of Investment Management, under delegated authority

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 87-5956 Filed 3-18-87; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-24204; File No. SR-DTC-87-03]

Self-Regulatory Organizations; Proposed Rule Change by the Depository Trust Co. Relating to Fees for Major Services

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78(b)(1), notice is hereby given that on February 24, 1987, The Depository Trust Company filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Depository Trust Company ("DTC") is filing herewith the changes in the fee schedule of major DTC services.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change, which will be effective for services provided after February 27, 1987, is to adjust the fees charged for various services to bring them closer to, or to, their respective estimated service costs for 1987.

The present schedule of major service fees was adopted by DTC's Board of Directors in December 1985 after consideration of Participant comment on a test fee schedule distributed in May 1985. That test schedule was based on a comprehensive cost study of DTC services completed in January 1985. That study, the first such analysis performed since 1980, showed that substantial disparities had developed between service unit costs and fees in the intervening five years. This resulted in many large fee changes in the May 1985 test fee schedule as compared to the fees then in effect. While various changes were made in the test schedule based on Participant comment, the service fees adopted in December 1985 which became effective May 1, 1986 represented another major step forward in DTC's effort to move service fees closer to service costs.

In order to prevent similar disparities between service costs and fees from arising in the future due to infrequent cost studies and fee changes, the DTC Board determined to adopt a new procedure which was stated in the depository's December 5, 1985 announcement to Participants of the new major fees, as follows:

In adopting new fees, the Board also declared its belief and intention that DTC should revise its basic fee schedule each year so that, through modest changes gradually over approximately five years, DTC service fees will be based on service cost in the absence of policy considerations which would justify limited exceptions. Large

changes in service fees after intervals of several years would thereby be avoided.

Following that procedure, the depository's Board of Directors recently completed a review of DTC's estimated service costs for 1987 and has adopted modest changes in a number of major service fees designed to move those fees closer to estimated 1987 service costs. This is the first of a series of gradual annual revisions of major service fees under this new procedure.

The proposed rule change is consistent with the requirements of the Securities and Exchange Act of 1934 and the rules and regulations thereunder applicable to DTC because the fees will more equitably be allocated among DTC Participants.

(B) Self-Regulatory Organization's Statement on Burden on Competition

DTC does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

DTC informed Participants and other users of its services of the proposed rule change by a memorandum dated January 12, 1987 entitled "1987 Revisions of Major Service Fees". Because Participants appear to support gradual moves toward cost-based fees and because, overall, the subject fee changes result in reduced fees, a formal period for Participant comment was not considered necessary this year.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3) of the Securities Exchange Act of 1934 and subparagraph (e) of Securities Exchange Act Rule 19b-4. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the

Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that

may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization.

All submissions should refer to the file number in the caption above and should be submitted by April 9, 1987.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: March 10, 1987.

Shirley E. Hollis,
Assistant Secretary.

1987 REVISIONS OF MAJOR SERVICE FEES

[NOTE.—All footnotes in this Annex are found at the end of the table]

Service	Present fee	Revised fee
Registered Securities		
I. Deposits: ^b		
The fee for deposits of certificates in active issues is determined by the time of receipt by DTC: ³		
Zone A—4:00 PM to 8:00 PM (Prior PM).....	\$1.00.....	\$1.20.....
Zone B—7:30 AM to 10:00 AM.....	\$1.80.....	\$2.00.....
Zone C—10:00 AM to 11:00 AM.....	\$4.00.....	\$4.20.....
Zone D—11:00 AM to 12:00 Noon.....	\$10.00.....	No change.....
Zone E—12:00 Noon to 1:00 PM.....	\$40.00.....	No change.....
The fee for deposits of certificates in less-active issues is determined by the time of receipt by DTC: ³		
Zone A—4:00 PM to 8:00 PM (Prior PM).....	\$1.60.....	\$1.90.....
Zone B—7:30 AM to 10:00 AM.....	\$2.40.....	\$2.70.....
Zone C—10:00 AM to 11:00 AM.....	\$4.60.....	\$4.90.....
Zone D—11:00 AM to 12:00 Noon.....	\$10.60.....	No change.....
Zone E—12:00 Noon to 1:00 PM.....	\$40.00.....	No change.....
A certificate charge per deposit per group of 10 certificates beyond the first 10 certificates in addition to the Zone fee.	\$0.30 per group of 10 certificates beyond the first 10 certificates.	No change.....
II. Withdrawals-by-Transfer (WTs): ^b		
For each assignment in an active issue submitted on PTS, API or CCF.....	\$1.05 per assignment.....	\$1.30 per assignment.....
For each separate paper assignment in an active issue.....	\$2.75 per assignment.....	\$3.00 per assignment.....
For each assignment in an active issue concluding in direct mail.....	\$0.55 per assignment.....	\$0.80 per assignment.....
For each assignment in less-active issue submitted on PTS, API or CCF.....	\$2.85 per assignment.....	\$3.10 per assignment.....
For each separate paper assignment in a less-active issue.....	\$4.55 per assignment.....	\$4.80 per assignment.....
For each assignment in a less-active issue concluding in direct mail.....	\$2.35 per assignment.....	\$2.60 per assignment.....
III. Urgent Withdrawals (CODs):		
For each urgent withdrawal requested on an overnight basis:		
Submitted by PTS.....	\$8.00 per withdrawal.....	\$8.50 per withdrawal.....
Submitted by paper.....	\$9.50 per withdrawal.....	\$10.00 per withdrawal.....
For each urgent withdrawal by PTS requested on a same-day basis.	\$14.00 per withdrawal.....	\$14.50 per withdrawal.....
For each urgent withdrawal submitted by paper requested on a same-day basis.	\$15.50 per withdrawal.....	\$16.00 per withdrawal.....
IV. Deliveries (Corporate Issues): ^c		
Deliver orders via CNS.....	\$0.10 for each item delivered or received.....	\$0.09 for each item delivered or received.....
Deliver orders via ID System.....	\$0.25 for each item delivered or received.....	\$0.21 for each item delivered or received.....
Deliver orders via PTS, API or CCF:		
For each deliver item presented:		
Prior PM.....	\$0.30 to the deliverer.....	\$0.25 to the deliverer.....
AM opening to 12:30 PM.....	\$0.55 to the deliverer.....	\$0.50 to the deliverer.....
Deliver orders via paper:		
Deliver.....	\$0.40 for each item received (regardless of time).	\$0.35 for each item received (regardless of time).
Receive.....	\$2.50 for each item delivered.....	\$2.50 for each item delivered.....
	\$0.40 for each item received.....	\$0.35 for each item received.....

1987 REVISIONS OF MAJOR SERVICE FEES—Continued

[NOTE.—All footnotes in this Annex are found at the end of the table]

Service	Present fee	Revised fee
V. ID Service:		
For each confirm distributed by paper, tape, PTS, CCF or dial-in terminal.	\$0.25 to broker (and \$0.25 for any interested party), \$0.25 to clearing agent if agent requests confirm; \$0.25 to investment manager ^c for each confirm received, whether or not affirmed.	\$0.22 to broker (and \$0.22 for any interested party), \$0.22 to clearing agent if agent requests confirm; \$0.22 to investment manager ^c for each confirm received, whether or not affirmed.
For each confirm transmitted in magnetic tape form.....	\$0.40 per confirm, plus telephone line costs.....	\$0.37 per confirm, plus telephone line costs.
For each confirm transmitted by facsimile device.....	\$0.45 per confirm, plus telephone line costs.....	\$0.42 per confirm, plus telephone line costs.
For each Pre-Authorized:		
Delivery Quantity (PDQ)	\$0.09 to the deliverer and to the receiver.....	No change.
Delivered/Not Delivered and Received Report line item.		
For each Unaffirmed Report line item.....	\$0.09 to the broker.....	No change.
For each Cumulative and Daily Eligible Trade Report line item.	\$0.09 to broker and clearing agent.....	No change.
For each Daily Eligible Trade Report line item	\$0.09 to broker for reports received by any interested party.	No change.
For each Ineligible Trade Report line item	\$0.09 to broker and clearing agent.....	No change.
VI. Long Position:		
For each active issue monthly (for registered corporate issues when a daily average of more than 15 Participants have position; for registered municipal bond issues when a daily average of more than 2 Participants have position).	\$0.58.....	\$0.55 per issue.
For each less-active registered corporate issue monthly (when a daily average of 15 or fewer Participants have position).	\$0.83 per issue.....	\$0.80 per issue.
For each less-active registered municipal issue monthly (when a daily average of 2 or fewer Participants have position).	\$1.33 per issue.....	\$1.30 per issue.
For each 100 shares or \$4,000 bonds (monthly) based on the average daily number of shares or bonds:		
0-25 million shares.....	\$0.0052.....	No change.
Excess over 25 million up to 200 million shares.....	\$0.0013.....	No change.
Excess over 200 million up to 300 million shares	\$0.000652.....	No change.
Excess over 300 million shares	\$0.00005.....	No change.
For each book-entry-only issue (monthly)	\$0.40 per issue; no per bond/per share charge.	No change.
VII. Reorganization:		
Mandatory Exchanges/Redemptions.....	\$20.00 per Participant position.....	\$21.00 per Participant position.
Voluntary Exchanges/Tender Offers	\$25.00 per letter of transmittal	\$28.00 per letter of transmittal.
Exit COD.....	\$20.00 per withdrawal.....	\$23.00 per withdrawal.
Warrant Subscriptions.....	Not applicable.....	Two DO fees, plus: \$20.00 per transaction minimum; \$.05 per share from 401 to 2,000 shares; \$100.00 per transaction maximum.
VIII. Underwritings:		
Corporate Issues	\$200.00 plus \$3.00 per million with a total maximum fee of \$2,000 and any unusual expenses.	\$205.00 plus \$3.00 per million with a total maximum fee of \$2,000 and any unusual expenses.
Registered Municipal Issues	Any book-entry-only issue: \$200.00 and any unusual expenses. Certificates of deposit: \$100.00 and any unusual expenses. \$400.00 plus \$3.00 per million with a maximum of \$2,000 ^a and any unusual expenses. Any book-entry-only issue: \$400.00 ^b and any unusual expenses.	Any book-entry-only issue: \$205.00 and any unusual expenses. Certificates of deposit: \$105.00 and any unusual expenses. \$405.00 plus \$3.00 per million with a maximum of \$2,000 ^a and any unusual expenses. Any book-entry-only issue: \$405.00 ^b and any unusual expenses.

1987 REVISIONS OF MAJOR SERVICE FEES—Continued

[NOTE.—All footnotes in this Annex are found at the end of the table]

Service	Present fee	Revised fee
IX. Dividends:		
For each cash dividend or interest payment:		
Corporate Issues.....	\$1.40 per credit.....	No change.
Registered Municipal Issues.....	\$1.40 per credit.....	\$1.60 per credit.
For each stock dividend payment.....	\$3.00 per credit.....	\$8.00 per credit.
X. PTS Reports:		
Inquiries, Unsolicited Messages and Messages:		
Participant inquires about security eligibility, aged WT instructions, and money settlement figures; messages about activities affecting a Participant's securities, etc.	\$0.08 per inquiry or message	\$0.06 per inquiry or message.
Reports:		
Dropped Deliveries Report.....	\$40.00 per month pre report series plus \$.08 per line.	\$30.00 per month pre report series plus \$.06 per line.
Dropped CODs Report.....	
Cash Dividend Report.....	
Pre-Update Edits:		
Allows a Participant to edit a DO or WT instruction prior to update by DTC's system.	\$0.08 per edit.....	\$0.06 per edit.
Broadcast:		
To send messages to other Participants in the DTC terminal network.	\$0.20 per 300 character message per addressee.	\$0.15 per 300 character message per addressee.
Bearer Bond Securities		
I. Deposits (by issue)	\$5.00 plus a charge after the first 10 certificates of \$2.00 per group of 10 certificates with a maximum total deposit charge of \$13.00.* Deposits between 12:00 noon and 1 p.m. for same day credit \$40.00. A bulk deposit is available under certain conditions.	\$4.70 plus a charge after the first 10 certificates of \$2.00 per group of 10 certificates with a maximum total deposit charge of \$12.70.* Deposits between 12:00 noon and 1 p.m. for same day credit \$40.00. A bulk deposit is available under certain conditions.
A surcharge per deposit of certificates without CUSIP numbers.	\$0.65 per deposit.....	No change.
II. Withdrawals (CODs):		
Overnight CODs:		
Submitted by PTS.....	\$8.25 plus a charge after the first ten certificates of \$4.00 per group of 10 certificates with a maximum total withdrawal charge of \$24.25*.	\$8.75 plus a charge after the first ten certificates of \$4.00 per group of 10 certificates with a maximum total withdrawal charge of \$24.75*.
Submitted by paper.....	\$10.75 plus a charge after the first 10 certificates of \$4.00 per group of 10 certificates, with a maximum total withdrawal charge of \$26.75*.	\$11.25 plus a charge after the first 10 certificates of \$4.00 per group of 10 certificates, with a maximum total withdrawal charge of \$27.25.*
III. Long Position:		
For each active issue per month (held by more than 2 Participants).	\$1.35 per issue	\$1.10 per issue.
For each less-active issue per month (held by one or two Participants).	\$2.10 per issue	\$1.85 per issue.
Monthly charge on face value:		
\$0 to \$.5 billion.....	0.000011.....	No change.
Excess over \$.5 billion up to \$1 billion.....	0.00000275	No change.
Excess over \$1 billion up to \$8 billion.....	0.000001375	No change.
Excess over \$8 billion	0.0000006875	No change.
A monthly surcharge on all positions in book Bond issues..	\$1.05 per issue	No change.
A monthly surcharge on all positions in issues requiring coupon collection from paying agents located outside the Metropolitan New York area.	\$0.50 per issue	No change.
VII. Deliver Orders (Registered Municipal Issues):		
Deliver orders via ID System	\$0.50 for each item delivered or received.....	\$0.21 for each item delivered or received.
Deliver orders via PTS, API or CCF:		
For each deliver item presented:		
Prior PM.....	\$0.55 to the deliverer.....	\$0.25 to the deliverer.

1987 REVISIONS OF MAJOR SERVICE FEES—Continued

[NOTE.—All footnotes in this Annex are found at the end of the table]

Service	Present fee	Revised fee
AM opening to 12:30 PM	\$0.80 to the deliverer..... \$0.65 for each item received (regardless of time).	\$0.50 to the deliverer. \$0.35 for each item received (regardless of time).
Deliver orders via paper:		
Deliver	\$2.75 for each item delivered.....	\$2.50 for each item delivered.
Receive	\$0.65 for each item received.....	\$0.35 for each item received.

^a For bearer securities, in a deposit or withdrawal of more than 150 certificates, each group of 150 certificates is charged as a separate deposit or withdrawal.

^b A Less-Active Issue fee is applicable when activity in any securities issue averages 2 or fewer activities on days when such issue has activity. Issues subject to Less-Active Issue fees in any quarter are identified by symbols in DTC's monthly Eligible Securities booklets based on activity in the previous three months measured. These fees may apply to Deposit, Withdrawal-by-Transfer and Long Position services.

^c This fee is shared equally by the broker and clearing agent for investmnet manager trades made by other than a trust department of direct and indirect depository Participants.

¹ Excludes deliveries in registered municipal bond issues.

² A surcharge of \$350.00 will apply to issues with a put option feature to cover the costs associated with reviewing the official statements and establishing a data base through which put periods are monitored. Issues requiring consultation and special development efforts will be charged an additional surcharge of \$500.00. The impact of these surcharges is not included in the weighted rates.

³ All deposits shipped to DTC from outside the NYC area will continue to be regarded as Zone A deposits.

[FR Doc. 87-5949 Filed 3-18-87; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

[License No. 03/03-0178]

D.C. Bancorp Venture Capital Co.; Filing of Application for Approval of a Conflict of Interest Transaction

Notice is hereby given that D.C. Bancorp Venture Capital Company, 1801 K Street, NW., Washington, DC 20006, a Federal Licensee under the Small Business Investment Act of 1958, as amended, (Act), has filed an application with the Small Business Administration (SBA) pursuant to section 312 of the Act and covered by § 107.903 of the SBA Rules and Regulations, governing Small Business Investment Companies (13 CFR 107.903) for approval of a conflict of interest transaction falling within the scope of the section of the Act and Regulations.

Subject to such approval, D.C. Bancorp Venture Capital Company proposes to provide funds to American PsychManagement, Inc. ("APM"), for the purposes of providing working capital.

The proposed financing is brought within the purview of § 107.903(b)(1) of the Regulations because Mr. Allan A. Weissburg, President of the Licensee and hence an Associate of the Licensee, has been a Director of APM for more than two years. According to § 107.3(f)(1) of the Regulations, APM is also an Associate of the Licensee.

Notice is hereby given that any interested person may, not later than fifteen (15) days from the date of publication of the notice, submit written comments on the proposed transaction

to the Deputy Associate Administrator for Investment, U.S. Small Business Administration, 1441 L Street, NW., Washington, DC 20416.

(Catalog of Federal Domestic Assistance Program No. 59.011. Small Business Investment Companies)

Dated: March 12, 1987.

Robert G. Lineberry,
Deputy Associate Administrator for Investment.

[FR Doc. 87-5929 Filed 3-18-87; 8:45 am]

BILLING CODE 8025-01-M

[License No. 03/03-0181]

Meridian Venture Partners; Issuance of a Small Business Investment Company License

On December 2, 1986, a notice was published in the **Federal Register** (51 FR 43488) stating that an application has been filed by Meridian Venture Partners, with the Small Business Administration (SBA) pursuant to § 107.102 of the Regulations governing small business investment companies (13 CFR 107.102 (1986)) for a license as a small business investment company.

Interested parties were given until close of business January 2, 1987, to submit their comments to SBA. No comments were received.

Notice is hereby given that, pursuant to section 301(c) of the Small Business Investment Act of 1958, as amended, after having considered the application and all other pertinent information, SBA issued License No. 03/03-0181 on February 24, 1987, to Meridian Venture Partners to operate as a small business investment company.

(Catalog of Federal Domestic Assistance Program No. 59.011. Small Business Investment Companies)

Dated: March 6, 1987.

Robert G. Lineberry,
Deputy Associate Administrator for Investment.

[FR Doc. 87-5930 Filed 3-18-87; 8:45 am]

BILLING CODE 8025-01-M

[Declaration of Disaster Loan Area #2269]

Mississippi; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on March 5, 1987, I find that Jones County in the State of Mississippi constitutes a disaster loan area because of severe storms, tornadoes and flooding occurring on February 28, 1987. Eligible persons, firms, and organizations may file applications for physical damage until the close of business on May 4, 1987, and for economic injury until the close of business on December 7, 1987, at:

Disaster Area 2 Office, Small Business Administration, Richard B. Russell Federal Building, 75 Spring Street, SW., Suite 822, Atlanta, Georgia 30303

or other locally announced locations.

The interest rates are:

Homeowners With Credit Available Elsewhere	8.000
Homeowners Without Credit Available Elsewhere	4.000
Businesses With Credit Available Elsewhere	7.500
Businesses Without Credit Available Elsewhere	4.000
Businesses (EIDL) Without Credit Available Elsewhere.....	4.000

Other (Non-Profit Organizations Including Charitable and Religious Organizations) 9.500

The number assigned to this disaster is 226912 for physical damage and for economic injury the number is 651000. (Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: March 6, 1987.

Bernard Kulik,

Deputy Associate Administrator for Disaster Assistance.

[FR Doc. 87-5926 Filed 3-18-87; 8:45 am]

BILLING CODE 8025-01-M

Region II Advisory Council; Public Meeting

The U.S. Small Business Administration, Region II Advisory Council, located in the geographical area of Syracuse, will hold a public meeting at 9:30 a.m. on Tuesday, April 7, 1987, Giovannis Ristorante, 2062 Erie Blvd., East Syracuse, New York, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call J. Wilson Harrison, District Director, U.S. Small Business Administration, 100 South Clinton Street, Room 1071, Syracuse, New York 13260. (315) 423-5371.

Jean M. Nowak,

Director, Office of Advisory Councils.

March 11, 1987.

[FR Doc. 87-5927 Filed 3-18-87; 8:45 am]

BILLING CODE 8025-01-M

Region V Advisory Council; Public Meeting

The U.S. Small Business Administration, Region V Advisory Council, located in the geographical area of Madison, Wisconsin, will hold a public meeting at 1:00 p.m. CST Thursday, April 23, 1987, at Vrakas, Blum & Co., S.C., Brookfield, Wisconsin, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call C.A. Charter, District Director, U.S. Small Business Administration, 212 East Washington Avenue, Room 213, Madison, Wisconsin 53703—(608) 264-5205.

Jean M. Nowak,
Director, Office of Advisory Councils.
March 13, 1987.

[FR Doc. 87-5928 Filed 3-18-87; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-87-3]

Petition for Exemption; Summary of Petitions Received and Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition

of petitions for exemption (14 CFR Part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR Chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATE: Comments on petitions received must identify the petition docket number involved and must be received on or before: April 8, 1987.

ADDRESS: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC-204), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

FOR FURTHER INFORMATION: The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC-204), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-3132.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR Part 11).

Issued in Washington, DC, on March 12, 1987.

John H. Cassady,
Assistant Chief Counsel, Regulations and Enforcement Division.

PETITIONS FOR EXEMPTION

Docket No.	Petitioner	Regulations affected	Description of relief sought
25165	HAL Aviation, Inc.	14 CFR 141.65	To allow petitioner to administer its own FAA-approved written tests for the flight instructor and airline transport pilot certificates and ratings.
24445	Air Transport Association of America	14 CFR 121.485	To allow member carriers to conduct flag operations on the understanding that § 121.485 only applies to an operation which requires three or more pilots and an additional flight crewmember.
24954	Seattle Jet Center	14 CFR 135.267	Petition for Reconsideration of Denial of Exemption No. 4705 to permit Seattle Jet Center to assign a flight crewmember and for its flight crewmembers to accept duty during flight time without having had at least 10 consecutive hours of rest during the 24-hour period preceding the planned completion of the assignment.
25150	Northwest Airlines, Inc.	14 CFR 121.433	To allow the flight attendants of Northwest Airlines, Inc., an extension of the 12-month requirement for recurrent training.
24085	Air Transport Association of America	14 CFR Part 121, Appendix H	To allow the member airlines of ATA and other similarly positioned carriers to accomplish total initial and upgrade pilot training and checking in a Phase II simulator.

DISPOSITIONS OF PETITIONS FOR EXEMPTION

Docket No.	Petitioner	Regulations affected	Description of relief sought
033CE	Beech Aircraft Corporation	Section 23.807(d)(1)	To allow a reduction in the number of required emergency exits on their MODEL 2000 Starship airplane when certificated to the commuter category.

DISPOSITIONS OF PETITIONS FOR EXEMPTION—Continued

Docket No.	Petitioner	Regulations affected	Description of relief sought
25101	Pacific Southwest Airlines, Inc.	14 CFR 121.371 and 121.378	To allow petitioner to use on its British-built BAe 146 aircraft certain engines, components, and spare parts that have been manufactured, repaired, over-hauled, or inspected by persons outside the United States who do not hold U.S. airman certificates.

PETITIONS FOR EXEMPTION

Docket No.	Petitioner	Regulations affected	Description of relief sought
25116	Clark Air Base Aero Club	14 CFR 91.171 and 91.172	To allow petitioner to utilize the U.S. Air Force, 3rd Tactical Fighter Wing (Maintenance Branch), in lieu of an FAA-certified repair station, to test and inspect the altimeter, transponder, and automatic pressure altitude reporting instrument on its U.S.-registered general aviation aircraft.

PETITIONS FOR EXEMPTION

Docket No.	Petitioner	Regulations affected	Description of relief sought, disposition
24427	United States Ultralight Foundation	14 CFR 103.1 (a), (b), (e)(1), and (e)(4)	To allow petitioner to operate powered ultralights of not more than 350 pounds empty weight, that have a power-off stall speed of not more than 29 knots calibrated airspeed, and with another occupant for the purpose of flight instruction. <i>Granted, February 18, 1987.</i>
24283	American Flyers	14 CFR 141.65	To allow petitioner to hold examining authority for flight instructor and airline transport pilot written tests. <i>Granted, February 13, 1987.</i>
25050	Blue Bell, Inc.	14 CFR 121.371(a) and 121.378	To allow petitioner to utilize the original equipment manufacturers and those foreign repair stations listed in Appendix A to this exemption as necessary to perform maintenance, preventive maintenance, and alterations outside of the United States on CL-44 aircraft listed in the operations specifications of the petitioner or on the engines or components of such aircraft. <i>Granted, February 18, 1987.</i>
23601	American West Management, Inc.	14 CFR 135.159(a)	To allow petitioner to substitute an approved third attitude indicator which meets the requirements of § 121.305(j) for the gyroscopic rate-of-return indicator. <i>Granted, February 18, 1987.</i>
24700	San Juan Airlines	14 CFR 135.225(e)(1)	To allow San Juan's pilots to take off under IFR at any Canadian civil airport listed in its operations specifications when the visibility minimum of any airport listed is less than 1 statute mile but not less than the minimums prescribed by Transport Canada. <i>Granted, February 17, 1987.</i>
23477	Experimental Aircraft Association	14 CFR 103.1 (a) and (e)(1)(4)	To allow individuals authorized by petitioner to operate powered ultralights at an empty weight of not more than 330 pounds, that have a power-off stall speed of not more than 29 knots calibrated airspeed, and with another occupant for the purpose of flight instruction. <i>Granted, February 12, 1987.</i>
24957	Stevens & Associates, Inc.	14 CFR 45.29	To allow the operation of a Cessna TR 182 while displaying 2-inch high nationality and registration marks (N-numbers) in place of the 12-inch high N-numbers now required. <i>Denied, February 6, 1987.</i>
24111	Ronald G. Shelly	14 CFR 21.187	To allow petitioner to apply for a standard airworthiness certificate in addition to the current experimental certificate for his Boeing A75N1 airplane and to determine the airworthiness of the aircraft when converted from one airworthiness classification to the other. <i>Denied, February 9, 1987.</i>
25075	Versatile Helicopters, Inc.	14 CFR 141.35(d)(3)(ii)	To allow Keith Hickman, President of Versatile Helicopters, Inc., to be designated as chief flight instructor without meeting certain experience requirements for such designation. <i>Denied, February 9, 1987.</i>
25052	TemSCO Helicopters, Inc., et al.	14 CFR 135.203(a)(1)	To allow day VFR operations below 500 feet above the surface. <i>Granted, February 9, 1987.</i>
24952	Metropolitan Dade County Fire Department	14 CFR 45.29	To allow petitioner to operate a Bell 412 rotorcraft displaying the petitioner's markings and 3-inch high nationality and registration marks (N-numbers), in place of the 12-inch high N-numbers now required. <i>Denied, February 9, 1987.</i>
030CE	Mooney Aircraft Corporation	14 CFR 23.991(a)(1)	To allow type certification of petitioner's Model M20L airplane with the Porsche PFM320N03 engine installed. <i>Granted, February 13, 1987.</i>
23863	MBB Helicopter Corp	14 CFR 47.65	Supplemental petition to permit petitioner to obtain an aircraft dealer's registration certificate without meeting the U.S. citizen requirements. <i>Granted, February 6, 1987.</i>

[FR Doc. 87-5881 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-13-M

Proposed Advisory Circular on Shoulder Harness-Safety Belt Installations**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of availability of proposed advisory circular (AC) and request for comment.

SUMMARY: The Federal Aviation Administration has proposed an advisory circular to provide information and guidance for installing shoulder harness and safety belt restraint systems at all seat locations in all aircraft previously type certified and in service. Accident experience has provided evidence that use of a shoulder harness in conjunction with a safety belt can reduce serious injuries and deaths. The information and guidance is intended to assure effective shoulder harness-safety belt installations are

made with consistent administration of the Federal Aviation Regulations.

DATE: Commenters must identify File AC No. 21-XX (AWS-120/AVN-100) and submit comments in duplicate on or before May 4, 1987.**ADDRESS:** Send all comments on the proposed advisory circular to: Technical Analysis Branch, AWS-120, Aircraft Engineering Division, Office of Airworthiness, File AC No. 21-XX (AWS-120/AVN-100), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; or

deliver comments to: Room 338, 800 Independence Avenue, SW., Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT:
Mr. Arthur J. Hayes, Technical Analysis Branch, AWS-120, Telephone (202) 267-9569.

SUPPLEMENTARY INFORMATION: A copy of the proposed AC may be obtained by contacting the person under "FOR FURTHER INFORMATION CONTACT."

Comment Invited

Interested persons are invited to comment on the proposed AC by submitting such written data, views, or arguments as they may desire. All comments received on or before the closing date for comments specified above will be considered by the Director of Airworthiness before issuing the final AC. The proposed AC and comments received may be examined in Room 338, FAA Headquarters Building (FOB-10A) 800 Independence Avenue, SW., Washington, DC 20591, between 8:30 a.m. and 4:30 p.m. weekdays except Federal holidays.

Issued in Washington, DC, on March 11, 1987.

William J. Sullivan,
Acting Director of Airworthiness.

[FR Doc. 87-5880 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-13-M

Air Traffic Control Tower; Martha's Vineyard Airport, MA; Notice of Commissioning

Notice is hereby given that on May 21, 1987, through September 30, 1987, the Airport Traffic Control Tower at the Martha's Vineyard Airport, Martha's Vineyard, Massachusetts, will be commissioned as a part-time Federal Aviation Administration (FAA) facility. Tower hours of operation will be established in advance by a Notice to Airmen, and thereafter be published in the Airman's Information Manual. The designated facility identification for the FAA airport control tower will be: *Vineyard Tower.*

This information will be reflected in the FAA organization statement.

Communications to the tower should be directed to: Federal Aviation

Administration, Airport Traffic Control Tower, P.O. Box 369, Vineyard Haven, Massachusetts 02568.

(Sec. 313(a), 72 Stat. 752; 49 USC 1354(a) and sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c))

Issued in Burlington, Massachusetts, on February 24, 1987.

Clyde DeHart, Jr.,
Acting Director, New England Region.
[FR Doc. 87-5879 Filed 3-18-87; 8:45 am]

BILLING CODE 4910-13-M

UNITED STATES INFORMATION AGENCY

Exchange Visitor Program; Skills List

AGENCY: United States Information Agency.

ACTION: Amendment to Exchange Visitor Skills List.

SUMMARY: The amendment to our Exchange Visitor Skills List, published in the *Federal Register* at 51 FR 34701, September 30, 1986, contained two incorrect dates.

DATE: This notice is effective immediately upon publication in the *Federal Register*.

ADDRESS: Comments and requests for further information should be addressed to: Richard L. Fruchterman, Assistant General Counsel, Office of the General Counsel and Congressional Liaison, USIA, Suite 700, 301 Fourth Street SW., Washington, DC 20547, telephone (202) 485-7976.

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of section 212(e) of the Immigration and Nationality Act, as amended (8 U.S.C. 1182(e)), the Secretary of State designated on April 25, 1972, a list of fields of specialized knowledge or skill (referred to as the Exchange Visitor Skills List) and those countries which clearly required the services of persons engaged in one or more of such fields. Any alien who was a national resident of one of those countries and obtained an exchange visitor visa and/or became a participant in an Exchange Visitor Program involving a designated field of specialized knowledge or skill after the effective date of that notice was subject to the 2-year foreign residence (home-

country physical presence) requirement of section 212(e) of said Immigration and Nationality Act as provided by said section and 22 CFR 41.65(b).

Pursuant to the provisions of Reorganization Plan No. 2 of 1977, section 217 of United States Information Agency Authorization Act of August 24, 1982 (Pub. L. 97-241) and Executive Orders Nos. 12048 (March 27, 1978) and 12388 (October 14, 1982) the Director, United States Information Agency, on June 12, 1984 further amended the 1972 Exchange Visitor Skills List, as revised in 1978, to increase the designated fields of specialized knowledge of skills. The 1984 amendment gave notice of the addition of China and the deletion of Cambodia, Iran and Viet-Nam from the skills list as well as the indefinite suspension of Afghanistan. The Exchange Visitor Skills List, as amended in 1984, is used in conjunction with the two prior existing lists. The Exchange Visitor Skills List, as amended in 1984, is further amended by the following changes:

1. South Africa is deleted from the list. Since South Africa was erroneously placed in the list in 1984, the change will take effect retroactively. Those exchange visitors from that country who entered the United States after July 12, 1984, are not subject to the residence requirement pursuant to the skills list. (Note: this date was formerly listed as June 12, 1984).

2. With regard to the deletion of South Africa and the corrections in the Chinese skills list for the Peoples Republic of China, this notice shall be retroactive to June 12, 1986. (Note: this date was formerly listed as December 12, 1984).

This notice amends Public Notice No. 356-37, 37 FR 8099-8177, April 25, 1972, Public Notice No. 591, 43 FR 5910-5912, February 10, 1978, Public Notice No. 49 FR 24194-24242, June 12, 1984, and 51 FR 34701, September 30, 1986.

Dated: March 12, 1987.

C. Normand Poirier,
Acting General Counsel and Congressional Liaison.

[FR Doc. 87-5889 Filed 3-18-87; 8:45 am]

BILLING CODE 8230-01-M

Sunshine Act Meetings

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 11:12 a.m. on Thursday, March 12, 1987, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to:

(A)(1) accept the bid submitted by First Interstate Bank of Oklahoma, National Association, Oklahoma City, Oklahoma, for the purchase of certain assets of and the assumption of the liability to pay deposits made in Expressway Bank, Oklahoma City, Oklahoma, which was expected to be closed by the Acting Bank Commissioner for the State of Oklahoma on Thursday, March 12, 1987; and (2) provide such financial assistance, pursuant to section 13(c)(2) of the Federal Deposit Insurance Act (12 U.S.C. 1823(c)(2)), as was necessary to facilitate the purchase and assumption transaction;

(B)(1) accept the bid submitted by First National Bank of Olney, Olney, Texas, a newly-chartered national bank, for the purchase of certain assets of and the assumption of the liability to pay deposits made in The First National Bank of Olney, Olney, Texas, which was expected to be closed by the Deputy Comptroller of the Currency, Office of the Comptroller of the Currency, on Thursday, March 12, 1987; and (2) provide such financial assistance, pursuant to section 13(c)(2) of the Federal Deposit Insurance Act (12 U.S.C. 1823(c)(2)), as was necessary to facilitate the purchase and assumption transaction; and

(C)(1) accept the highest acceptable bid which may be submitted in accordance with the "Instructions for Bidding" for a purchase and assumption transaction, or (2) in the event no acceptable bid for a purchase and assumption transaction is submitted, accept the highest acceptable bid for an insured deposit transfer transaction which may be submitted, or (3) in the event no acceptable bid for either type transaction is submitted, make funds available for the payment of the insured deposits of the closed bank, with respect to each of the following: (a) Plaza National Bank, Del Rio, Texas, which was expected to be closed by the Deputy Comptroller of the Currency, Office of the Comptroller of the Currency, on Thursday,

March 12, 1987; (b) Western Bank, El Paso, Texas, which was expected to be closed by the Banking Commissioner for the State of Texas on Thursday, March 12, 1987; and (C) Beaver Creek State Bank, Beaver Creek, Minnesota, which was expected to be closed by the Commissioner of Commerce for the State of Minnesota on Friday, March 13, 1987.

At that same meeting, the Board also considered matters related to the possible closing of another insured bank.

In calling the meeting, the Board determined, on motion of Director C.C. Hope, Jr. (Appointive), seconded by Mr. Robert J. Herrmann, acting in the place and stead of Director Robert L. Clarke (Comptroller of the Currency), concurred in by Chairman L. William Seidman, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: March 16, 1987.

Federal Deposit Insurance Corporation
Hoyle L. Robinson,
Executive Secretary.

[FR Doc. 87-6107 Filed 3-17-87; 2:49 pm]
BILLING CODE 6714-01-M

FEDERAL ELECTION COMMISSION

DATE AND TIME: Tuesday, March 24, 1987, 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

* * * * *

DATE AND TIME: Thursday, March 26, 1987, 10:00 a.m.

Federal Register

Vol. 52, No. 53

Thursday, March 19, 1987

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Setting of Dates for Future Meetings.
Correction and Approval of Minutes.
Draft Advisory Opinion 1987-7—Frank M. Northam on behalf of the United States Defense Committee and Patrick Reilly, Public Financing of Presidential Candidates—Revised Proposed Regulations
Routine Administrative Matters.

PERSON TO CONTACT FOR INFORMATION:
Mr. Fred Eiland, Information Officer, Telephone: 202-376-3155.

Marjorie W. Emmons,
Secretary of the Commission.

[FR Doc. 87-6063 Filed 3-17-87; 2:15 pm]

BILLING CODE 6715-01-M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

March 13, 1987.

TIME AND DATE: 10:00 a.m., Thursday, March 19, 1987.

PLACE: Room 600, 1730 K Street, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. *Southern Ohio Coal Company*, Docket Nos. WEVA 86-190-R, etc. [Issues include consideration of a petition for discretionary review.]

2. *Odell Maggard v. Chaney Creek Coal Corp., etc.*, Docket Nos. KENT 86-1-D, etc. [Issues include whether the administrative law judge erred in sustaining the complainant's discrimination complaint.]

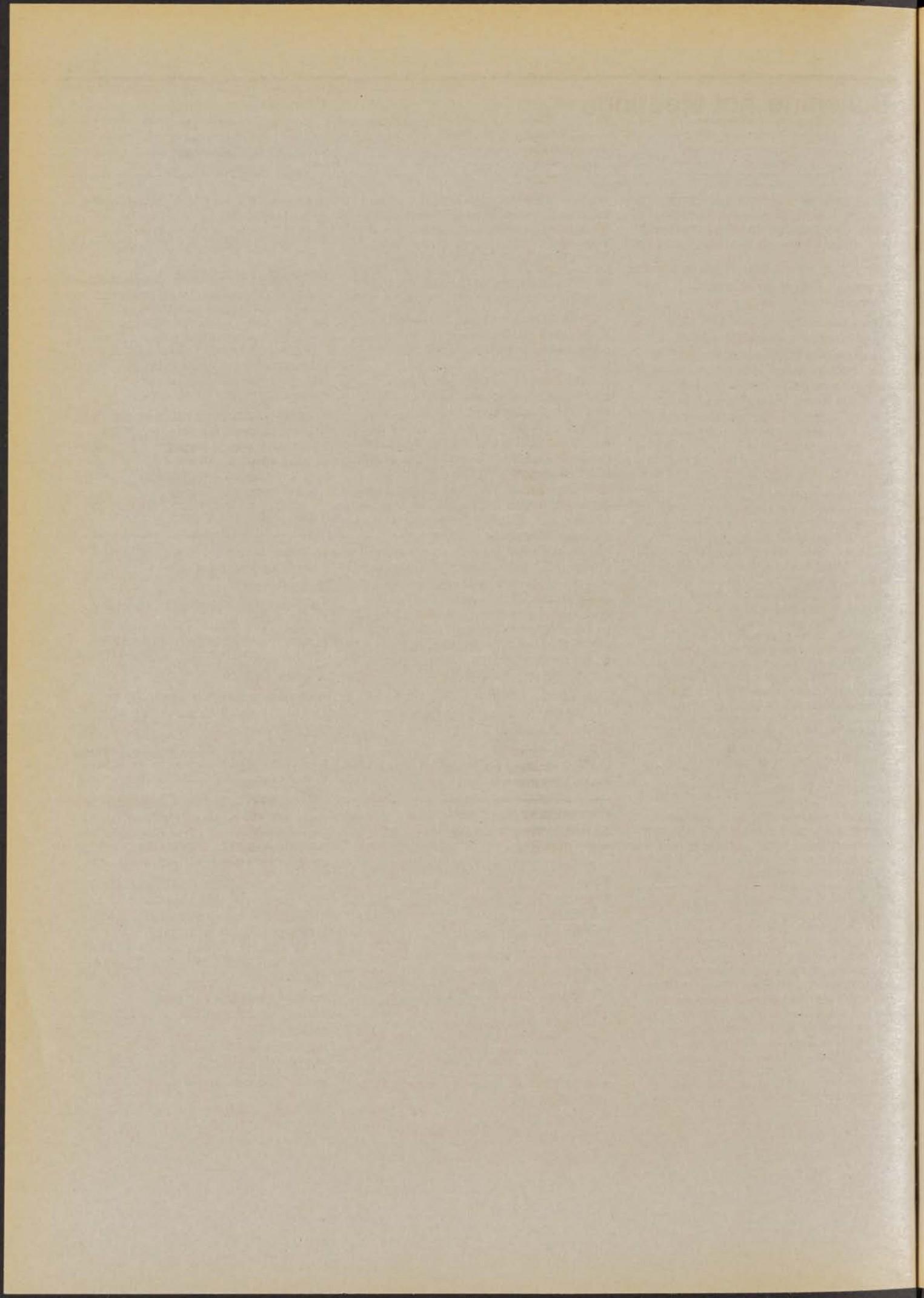
Any person intending to attend this meeting who requires special accessibility features such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 20 CFR 2706.150(a)(3) and 2706.160(e).

CONTACT PERSON FOR MORE INFORMATION:

Jean Ellen (202) 653-5629.
Jean H. Ellen,
Agenda Clerk.

[FR Doc. 87-6078 Filed 3-17-87; 1:15 pm]

BILLING CODE 6735-01-M



Final Rule
Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities; Final Rule

Thursday
March 19, 1987

Part II

**Environmental
Protection Agency**

40 CFR Part 265

Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities; Final Rule

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 265**

[SW-FRL-3092-1]

Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities; Final Rule**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: The Environmental Protection Agency is today amending the interim status regulations for closing and providing postclosure care for hazardous waste surface impoundments (40 CFR Part 265, Subpart K), under the Resource Conservation and Recovery Act (RCRA).

The Agency proposed today's modifications to the interim status standards on July 26, 1982. Today's amendments provide conformance between certain interim status requirements for surface impoundments and those requirements contained in the permitting rules of 40 CFR Part 264, that were also published on July 26, 1982. The Agency is also setting forth its interpretation of the regulatory requirements applying to closure of storage facilities regulated under both permits and interim status.

EFFECTIVE DATE: These final regulations become effective on September 15, 1987, which is six months from the date of promulgation, as RCRA section 3010(b) requires.

ADDRESS: The docket for this rulemaking (Docket No. F-87-CCF-FFFFF) is located in Room MLC100, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC and is available for viewing from 9:00 a.m. to 3:30 p.m., Monday through Friday, excluding holidays. Call Mia Zmud at 475-9327 for appointments.

FOR FURTHER INFORMATION CONTACT: RCRA hotline at (800) 424-9346 (in Washington, DC, Call 382-3000) or for technical information contact Ossi Meyn, Office of Solid Waste (WH-565E), U.S. Environmental Protection Agency, Washington, DC 20460, telephone (202) 382-4654.

SUPPLEMENTARY INFORMATION:**I. Authority**

These regulations are issued under the authority of sections 1006, 2002(a), 3004 and 3005 of the Solid Waste Disposal Act (SWDA), as amended by the Resource Conservation and Recovery

Act (RCRA) of 1976, as amended (42 U.S.C. 6905, 6912(a), 6924, and 6925).

II. Background

Subtitle C of RCRA creates a "cradle-to-grave" management system intended to ensure that hazardous waste is safely treated, stored, or disposed. First, Subtitle C requires the Agency to identify hazardous waste. Second, it creates a manifest system designed to track the movement of hazardous waste, and requires hazardous waste generators and transporters to employ appropriate management practices as well as procedures to ensure the effective operation of the manifest system. Third, owners and operators of treatment, storage, and disposal facilities must comply with standards the Agency established under section 3004 of RCRA that "may be necessary to protect human health and the environment." Ultimately, these standards will be implemented exclusively through permits issued to owners and operators by authorized States or the Agency. However, until these permits are issued, existing facilities are controlled under the interim status regulations of 40 CFR Part 265 that were largely promulgated on May 19, 1980. Under RCRA interim status, the owner or operator of a facility may operate without a permit if: (1) It existed on November 19, 1980, (or it existed on the effective date of statutory or regulatory changes under RCRA that render the facility subject to the requirements to have a permit under section 3005); (2) he has complied with the notification requirements of section 3010 of RCRA; (3) he applied for a permit (Part A application) in accordance with section 3005 of RCRA. Interim status is retained until the regulatory agency makes a formal decision to issue or deny the permit or until the facility loses its interim status by statute for failure to submit Part B permit application and/or certification of compliance with applicable groundwater monitoring and financial assurance requirements.

In regulations promulgated on July 26, 1982, [40 CFR Part 264, 47 FR 32274], the Agency established permitting standards in 40 CFR Part 264 covering the treatment, storage, and disposal of hazardous wastes in surface impoundments, waste piles, land treatment units, and landfills. Owners and operators of such facilities must meet these standards to receive RCRA permits. Also included in the Federal Register on that date were a series of changes to the interim status requirements of Part 265, which were promulgated to ensure consistency with

the new Part 264 standards. There were, however, a few additional Part 265 conforming changes that the Agency believed should first be proposed for public comment because, in most cases, the public had not had sufficient opportunity to comment on the appropriateness of applying them during the interim status period. Many of the changes that were proposed on July 26, 1982, were promulgated in final regulations on April 23, 1985 (50 FR 16044). Today, the Agency is making final the remaining changes to the surface impoundment closure and post-closure care requirements (§ 265.228) that were proposed on July 26, 1982.

III. Discussion of Today's Amendments

The Part 264 rules issued on July 26, 1982, for surface impoundment closure and post-closure care (§§ 264.228 and 264.310) are in many ways similar to the interim status requirements (§§ 265.228 and 265.310). The Part 264 closure rules, however, contain more specific performance standards to assure adequate protection of human health and the environment. For reasons discussed below, the Agency believes the more explicit Part 264 closure rules should also be implemented during interim status. Moreover, EPA believes that the closure process is adequate to apply these closure requirements. The existing review process for interim status closure and post-closure care plans will provide an opportunity for the Agency to review the specifics of the plans for compliance with the closure performance standards. Thus, any problems with misinterpretation of the closure requirements by the owner or operator would be identified and rectified prior to actual closure. In fact, the review process for closure and post-closure care plans during interim status is similar to the review process of closure and post-closure care plans conducted during the permitting process. Therefore, the Agency believes that these closure requirements are capable of being properly implemented during interim status.

The § 265.228 closure rules proposed on July 26, 1982, and promulgated today, retain the basic format of existing regulations by allowing owners and operators to choose between removing hazardous wastes and waste residues (and terminating responsibility for the unit) or retaining wastes and managing the unit as a landfill. (An additional choice for closure is proposed elsewhere in today's *Federal Register*.) The requirements for both choices are made more specific in today's amendments.

If the owner or operator chooses not to remove or decontaminate the waste and waste residues, then the rules promulgated today provide that the owner or operator must: (1) Eliminate free liquids by either removing them from the impoundment or solidifying them, (2) stabilize the remaining waste and waste residues to support a final cover, (3) install a final cover to provide long-term minimization of infiltration into the closed impoundment, and (4) perform post-closure care and ground-water monitoring.

The Part 265 regulations promulgated today (like the existing Part 264 regulations for permitted units) allow owners and operators of surface impoundments to remove or decontaminate wastes to avoid capping and post-closure care requirements (§ 265.228(a)(1)). They must remove or decontaminate all wastes, waste residues, contaminated containment system components (e.g., contaminated portions of liners), contaminated subsoils, and structures and equipment contaminated with waste and leachate. All removed residues, subsoils, and equipment must be managed as hazardous waste unless there is compliance with the delisting provisions of § 261.3(d). (Similar Part 265 closure and post-closure care rules for waste piles were promulgated on July 26, 1982.)

The new requirements for closure by removal differ significantly from the previous Part 265 requirements in one respect. The previous interim status requirement in § 265.228(b) required owners or operators to remove all waste residuals and contaminated soil or to demonstrate, using the procedures in § 261.3(c) and (d), that the materials remaining at any stage of the removal were no longer a hazardous waste. Once an owner or operator made a successful demonstration under § 261.3(c) and (d), (s)he could discontinue removal and certify closure.

Under § 261.3(c) and (d), materials contaminated with listed waste (as evidenced by the presence of Appendix VIII constituents) are hazardous waste by definition unless the material is delisted. Materials contaminated with characteristic wastes, however, are only hazardous wastes to the extent that the material itself exhibits a characteristic. Thus to meet the old closure by removal standard, owners or operators of characteristic waste impoundments had only to demonstrate that the remaining material did not exhibit the characteristic that first brought the impoundment under regulatory control.

This demonstration, however, arguably allowed significant and potentially harmful levels of hazardous

constituents (i.e., those contained in Appendix VIII of Part 261) to remain in surface impoundment units without subjecting the units to landfill closure, post-closure care, or monitoring requirements.

For example, the previous version of the rule allowed residues from waste that originally exhibited the characteristic of extraction procedure (EP) toxicity to remain in place at "clean closure" if the residue was no longer EP toxic. This could allow an environmentally significant quantity of hazardous constituents to remain at a facility site that will receive no further monitoring or management. While EP toxic criterion would preclude only a concentration that exceeds 100 times the drinking water standard, constituents may remain at levels significantly above the drinking water standards. If such constituents are close to the saturated zone, they may contaminate ground water at levels exceeding the ground-water protection standard. Furthermore, the waste residues may contain significant and potentially harmful levels of other hazardous constituents (listed in Appendix VIII of Part 261) that are not found through EP testing. Hence, the language "or demonstrate what remains is no longer a hazardous waste" has been dropped from the interim status regulations because it is inconsistent with the overall closure performance standard requiring units to close in a manner that eliminates or minimizes the post-closure escape of Appendix VIII constituents.

Making this conforming change ensures that no Appendix VIII constituent presents any threat to human health and the environment. This is also consistent with several of the new requirements added by the Hazardous and Solid Waste Amendments of 1984. For example, new section 3004(u) of PCRA requires corrective action for releases not only of hazardous wastes, but also hazardous constituents. Similarly, section 3001(f) requires the Agency to consider, when evaluating waste delisting petitions, all hazardous constituents found in the waste, not just those for which the waste was listed as hazardous. Finally, new section 3005(i) requires owners and operators of landfills, surface impoundments, waste piles, or land treatment units that qualify for interim status and receive waste after July 26, 1982, to meet the ground-water monitoring and corrective action standards found in Subpart F to 40 CFR Part 264. These regulations also require owners and operators to monitor and clean up the full range of Appendix VIII constituents found in a waste.

The question has also arisen during the implementation of previous closures by removal whether § 265.228 requires consideration of potential ground-water contamination in addition to soil contamination. The answer to this question is yes. The closure by removal requirements in § 265.228(a)(1) and (b) require removal or decontamination (i.e., flushing, pumping/treating the aquifer) of "underlying and surrounding contaminated soils." Since contamination of both saturated and unsaturated soils may threaten human health or the environment, the Agency interprets the term "soil" broadly to include both unsaturated soils and soils containing ground water. Thus the closure by removal standard requires consideration of both saturated and unsaturated soils. Uncontaminated ground water is, therefore, a requirement for "clean closure" under Part 265 (and Part 264) as revised today as well as under the previous regulation.

The one comment received on the proposed § 265.228 surface impoundment closure and post-closure care requirements for "clean closure" argued that clay liners should be allowed to remain in place at closure even if they are contaminated because their excavation is expensive and hazardous to workers removing the waste. EPA disagrees. While excavation may be expensive, the additional cost of removing the liner will usually be small in comparison to the cost of removing the waste. Therefore, if an owner or operator is willing to expend the resources to remove the waste, it is not unduly burdensome to go one step further and remove the liner. This burden is justified by the benefit of removing contamination from the impoundment. (See discussion below.) If extensive excavation is needed, thereby considerably increasing the cost of removal, it is generally because extensive contamination of the clay and underlying soils has occurred. In these cases, it may be cheaper to install a proper final cover and perform post-closure care rather than remove the contamination. In addition, we do not believe that removal of the liner will be any more hazardous to workers than is the removal of the waste. With proper safety procedures, removal of the waste and liner should not pose an undue hazard to workers.

EPA's Interpretation of the "Remove or Decontaminate" Standard

The sole commenter on the proposed rule also suggested that, in addition to the case where all wastes, residues, and contaminated liners and soils are

removed, no final cover should be required where the type and quantity of waste in the liner can be shown to pose no public health or environmental threat. This comment touches upon an issue that has arisen in other contexts, that is: What is the necessary extent of removal or decontamination of wastes, waste residues, contaminated liners, and soils (including contaminated ground water) to avoid the landfill closure and post-closure care requirements under both Parts 264 and 265 regulations? The issue concerning how much removal or decontamination of wastes and waste residues is necessary to protect human health and the environment is relevant in a broad range of regulatory contexts currently being examined by the Agency including closure and corrective actions under RCRA and response actions under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) programs.

The removal and decontamination issue arises directly from differences in regulatory strategy between disposal and storage. A storage unit holds wastes temporarily, and the wastes are eventually removed for treatment or disposal elsewhere. The goal at closure is to leave no materials at the storage site that require further care. In contrast, a disposal unit, by definition, is closed with wastes and residues remaining at the site. The goal at closure is to assure that these remaining wastes and residues are managed in a manner that protects human health and the environment. There is no need for post-closure oversight of storage units since all potentially harmful wastes and contaminated materials are removed. This is not true for disposal units; hence, the Agency has promulgated regulations requiring post-closure care for disposal units. (For further discussions on a proposed alternative closure option, see the preamble to proposed §§ 264.310 and 265.310 elsewhere in today's Federal Register).

To assist the reader, we describe below EPA's interpretation of the "remove and decontaminate" language in §§ 264.228 and 265.228, i.e. we describe the amount of removal or decontamination that obviates the need for post-closure care for both interim status and permitted surface impoundment units. With regard to storage units regulated under both Parts 264 and 265, the Agency interprets the terms "remove" and "decontaminate" to mean removal of all wastes and liners, and the removal of leachate and materials contaminated with the waste or leachate (including ground water).

that pose a substantial present or potential threat to human health or the environment. The Agency recognizes that at certain sites limited quantities of hazardous constituents might remain in the subsoil and yet present only insignificant risks to human health and the environment. Because regulations for storage facilities require no further post-closure care, the Agency must be certain that no hazardous constituents remain that could harm human health or the environment (now or in the future). To provide the necessary level of assurance, the Agency will require owners or operators to remove all wastes and contaminated liners and to demonstrate that any hazardous constituents left in the subsoils will not cause unacceptable risks to human health or the environment. The Agency will review site-specific demonstrations submitted by facility owners and operators that document that enough removal and decontamination has occurred so that no further action is necessary. Owners or operators wishing to avail themselves of the site-specific removal option must include in their closure plans specific details of how they expect to make the demonstration, including sampling protocols, schedules, and the exposure level that is intended to be used as a standard for assessing whether removal or decontamination is achieved (see discussion below). The Agency is presently developing a guidance document explaining the technical requirements for achieving a "clean closure". This guidance document should be available in draft form by January 1987. In the meantime, the following discussion presents the framework for the demonstration procedure.

The closure demonstrations submitted by facility owners and operators must document that the contaminants left in the subsoils will not impact any environmental media including ground water, surface water, or the atmosphere in excess of Agency-recommended limits or factors, and that direct contact through dermal exposure, inhalation, or ingestion will not result in a threat to human health or the environment. Agency recommended limits or factors are those that have undergone peer review by the Agency. At the present time these include water quality standards and criteria (Ambient Water Quality Criteria 45 FR 79318, November 28, 1980; 49 FR 5831, February 15, 1984; 50 FR 30784, July 29, 1985), health-based limits based on verified reference doses (RfDs) developed by the Agency's Risk Assessment Forum (Verified Reference Doses of USEPA, ECAO-CIN-475,

January 1986) and Carcinogenic Potency Factors (CPF) developed by the Agency's Carcinogen Assessment Group (Table 9-11, Health Assessment Document for Tetrachloroethylene (Perchloroethylene) USEPA, OHEA/600/8-82/005F, July 1985) to be used to determine exposure at a given risk, or site-specific Agency-approved public health advisories issued by the Agency for Toxic Substance and Disease Registry of the Center for Disease Control, Department of Health and Human Services.

The Agency is currently compiling toxicity information on many of the hazardous constituents contained in Appendix VIII to Part 261. The facility owner and operators should check with the Office of Solid Waste, Characterization and Assessment Division, Technical Assessment Branch (202) 382-4761 for the latest toxicity information. However, for some hazardous constituents, formally recommended exposure limits do not yet exist. If no Agency recommended exposure limits exist for a hazardous constituent then the owner or operator must either remove the constituent down to background levels, submit data of sufficient quality for the Agency to determine the environmental and health effects of the constituent, or follow landfill closure and post-closure requirements. Data submitted by the owner or operator on environmental and health effects of a constituent should, when possible, follow the toxicity testing guidelines of 40 CFR Parts 797 and 798 (50 FR 39252, September 27, 1985). The Agency does not believe there are many situations where developing exposure levels will be a realistic option for owners and operators because the testing required by 40 CFR Parts 797 and 798 to produce reliable toxicity estimates is expensive and time-consuming.

The Agency believes it is necessary to present policy on the appropriate point of exposure for the various pathways of exposure in order to provide some national consistency in dealing with the potential impacts of the release of hazardous constituents from closing units. The following point of exposure was chosen because the Agency believes it represents a realistic and at the same time reasonably conservative estimate of where either environmental or human receptors could be exposed to the contaminants released from the unit. For the purpose of making a closure by removal demonstration, the potential point of exposure to hazardous waste constituents is assumed to be directly at or within the unit boundary for all

routes of exposure (surface-water contact, ground-water ingestion, inhalation, and direct contact). Potential exposure at or within the unit boundary must be assumed because no further oversight or monitoring of the unit is required if the unit is closed by removal. (Recall that the land overlying a unit that closes by removal may be transferred and developed freely without giving notice of its prior use.) Therefore, no attenuation of the hazardous waste constituents leaching from the waste residues can be presumed to occur before the constituents reach exposure points.

This approach differs from the existing "delisting procedure" developed in response to the requirements of §§ 261.3 (c) and (d), 260.20, and 260.22. As discussed previously, the "clean closure" approach is based on the premise that, after closure by removal is satisfied, no further management control over the waste (or unit) is necessary. In contrast, delisted solid waste remains subject to the regulatory controls promulgated by the Agency under Subtitle D of RCRA. Subtitle D contains performance criteria for the management of non-hazardous waste. Although the Agency is currently assessing whether more specific Federal regulatory requirements are needed for waste management under Subtitle D, most states have already adopted specific regulatory requirements for Subtitle D waste management. Therefore, even though a waste may be delisted its management continues to be controlled. In contrast, closure by removal will not be followed by any regulatory controls; hence, an environmentally conservative approach is needed to assure no further risk to human health and the environment. Therefore, unlike the current "delisting procedure" that is based on a generic process that only considers the ground-water route of exposure, the demonstration procedure discussed here is waste-specific and site-specific, considers all potential exposure pathways, and assumes no attenuation.

The demonstration should be conservative in the sense that it eliminates the uncertainties associated with contaminant fate and transport, focusing on the waste contaminant levels and contaminant characteristics. Therefore, arguments relying on fate and transport calculations will not be accepted. The Agency is pursuing this relatively conservative approach at this time because we are confident that it will be protective of human health and the environment. After a few years of experience with "clean closure"

demonstrations, the Agency may decide that a less stringent approach is sufficiently reliable to assure that closures based on such analyses are fully protective of human health and the environment. At that time, the Agency may change its position on the use of fate and transport arguments for "clean closure" demonstrations. (Elsewhere in today's *Federal Register*, the Agency is proposing a third closure option that would incorporate fate and transport factors. However, unlike the closure by removal option, that option would require closure to be followed by verification monitoring to verify the fate and transport predictions and assume that the closure protects human health and the environment.)

To make the demonstration with respect to the direct contact pathway, owners or operators must demonstrate that contaminant levels in soil are less than levels established by the Agency as acceptable for ingestion or dermal contact. Total waste constituent levels in soil should be used for this analysis. Arguments based on exposure control measures such as fencing or capping will not be acceptable since the long-term future use of the property cannot be reliably controlled and hence the long-term effectiveness of these measures is uncertain.

To make the demonstration with respect to the ground-water pathway, owners or operators must remove enough contaminated soil and saturated subsoils (i.e., ground water) to demonstrate that constituent levels in ground water do not exceed Agency-established chronic health levels (based on Rfd or CPF values) and that residual contaminant levels remaining in the soil will not contribute to any future contamination of ground water. (Note: this demonstration may in some cases require constituent-specific ground water data beyond that required by §§ 265.90 through 2165.100). The demonstration related to residual soil contamination levels must show that levels of constituents found in leachate from the residual soil contamination are not above Agency-established exposure levels. Levels of constituents in leachate may be estimated based on known characteristics of the waste constituents (e.g., solubility and partitioning coefficients) or determined by the results of actual soil leaching tests. The Agency is exploring the appropriateness of using the extraction procedures (but not the acceptable contaminant levels) found in the Toxicity Characteristics Leaching Procedure (TCLP), *Federal Register* of January 14, 1985 (51 FR 1690). The current EP Toxicity leaching

procedure is insufficient for this demonstration because it does not capture the organic constituents in the waste.

The analysis of potential air exposures should assess contaminants migrating from the soils into the atmosphere. The demonstration should include emission calculations, available monitoring data, and safe inhalation levels based on Agency-established exposure levels.

The potential surface water exposure analysis should compare Agency-established water quality standards and criteria (45 FR 79318, November 28, 1980) with the levels of constituents that may leach from the residual contaminated soil. Tests described previously should be used to estimate the level of constituents in the leachate. The surface water exposure analysis should also consider existing surface water contaminant concentrations.

IV. State Authority

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA program within the State. (See 40 CFR Part 271 for the standards and requirements for authorization.) Following authorization, the Agency retains enforcement authority under sections 3008, 7003 and 3013 of RCRA, although authorized States have primary enforcement responsibility.

Prior to the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final authorization administered its hazardous waste program entirely in lieu of the Federal program. The Federal requirements no longer applied in the authorized State, and the Agency could not issue permits for any facilities in a State where the State was authorized to permit. When new, more stringent Federal requirements were promulgated or enacted, the State was obligated to enact equivalent authority within specified time frames. New Federal requirements did not take effect in an authorized State until the State adopted the requirements as State law.

In contrast, under section 3006(g) of RCRA, 42 U.S.C. 6926(g), new requirements and prohibitions imposed by HSWA take effect in authorized States at the same time that they take effect in nonauthorized States. The Agency is directed to carry out those requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted

authorization to do so. While States must still adopt HSWA-related provisions as State law to retain final authorization, the HSWA applies in authorized States in the interim.

B. Effect on State Authorization

Today's rule promulgates standards that are not effective in authorized States since the requirements are not being imposed pursuant to Hazardous and Solid Waste Amendments of 1984. Thus, the requirements will be applicable only in those States that do not have final authorization. In authorized States, the requirements will not be applicable until the State revises its program to adopt equivalent requirements under State law.

40 CFR 271.21(e)(2) requires that States that have final authorization must modify their programs to reflect Federal program changes and must subsequently submit the modification to EPA for approval. The deadline by which the State must modify its program to adopt today's rule is July 1988. These deadlines can be extended in exceptional cases (40 CFR 271.21(e)(3)). Once EPA approves the revision, the State requirements become Subtitle C RCRA requirements.

States with authorized RCRA programs may already have requirements similar to those in today's rule. These State requirements have not been assessed against the Federal regulations being promulgated today to determine whether they meet the tests for authorization. Thus, a State is not authorized to carry out these requirements in lieu of the Agency until the State requirements are approved. Of course, States with existing standards may continue to administer and enforce their standards as a matter of State law.

States that submit official applications for final authorization less than 12 months after the effective date of these standards are not required to include standards equivalent to these standards in their application. However, the State must modify its program by the deadlines set forth in § 271.21(e). States that submit official applications for final authorization 12 months after the effective date of those standards must include standards equivalent to these standards in their application. 40 CFR 271.3 sets forth the requirements a State must meet when submitting its final authorization application.

V. Effective Date

Pursuant to section 3010(b) of RCRA, today's amendments will be effective six months after promulgation.

VI. Regulatory Impact

Under Executive Order 12291, the Agency must judge whether a regulation is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. As stated in the proposed rule on July 26, 1982, the Agency does not believe these conforming changes will result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or in domestic or export markets. In addition, the Part 265 conforming changes do not impose any requirements beyond those required for permitting facilities under Part 264. Therefore, the Agency believes that today's rule is not a major rule under Executive Order 12291.

This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

VII. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, (5 U.S.C. 601 *et seq.*), the Agency must prepare a regulatory flexibility analysis for all regulations that may have a significant impact on a substantial number of small entities. The Agency conducted such an analysis on the land disposal regulations and published a summary of the results in the *Federal Register*, Vol. 48, No. 15 on January 21, 1983. Today's conforming regulation does not impose significant additional burdens. In addition, they do not impose any requirements beyond those required for permitting facilities under Part 264.

VIII. Paperwork Reduction Act

The certification requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number 2050-0008.

List of Subjects in 40 CFR Part 265

Hazardous materials, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Waste treatment and disposal, Water supply.

Dated: March 8, 1987.

Lee M. Thomas,
Administrator.

For the reasons set out in the preamble, Part 265, Subpart K of Title 40

of the Code of Federal Regulations is amended as follows:

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

1. The authority citation for Part 265 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3004, and 3005 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), 6924, and 6925).

2. In 40 CFR Part 265, Subpart K, § 265.228 is revised to read as follows:

§ 265.228 Closure and post-closure care.

(a) At closure, the owner or operator must:

(1) Remove or decontaminate all waste residues, contaminated containment system components (liners, etc.), contaminated subsoils, and structures and equipment contaminated with waste and leachate, and manage them as hazardous waste unless § 261.3(d) of this chapter applies; or

(2) Close the impoundment and provide post-closure care for a landfill under Subpart G and § 265.310, including the following:

(i) Eliminate free liquids by removing liquid wastes or solidifying the remaining wastes and waste residues;

(ii) Stabilize remaining wastes to a bearing capacity sufficient to support the final cover; and

(iii) Cover the surface impoundment with a final cover designed and constructed to:

(A) Provide long-term minimization of the migration of liquids through the closed impoundment;

(B) Function with minimum maintenance;

(C) Promote drainage and minimize erosion or abrasion of the cover;

(D) Accommodate settling and subsidence so that the cover's integrity is maintained; and

(E) Have a permeability less than or equal to the permeability of any bottom liner system or natural subsoils present.

(b) In addition to the requirements of Subpart G, and § 265.310, during the post-closure care period, the owner or operator of a surface impoundment in which wastes, waste residues, or contaminated materials remain after closure in accordance with the provisions of paragraph (a)(2) of this section must:

(1) Maintain the integrity and effectiveness of the final cover, including making repairs to the cover as

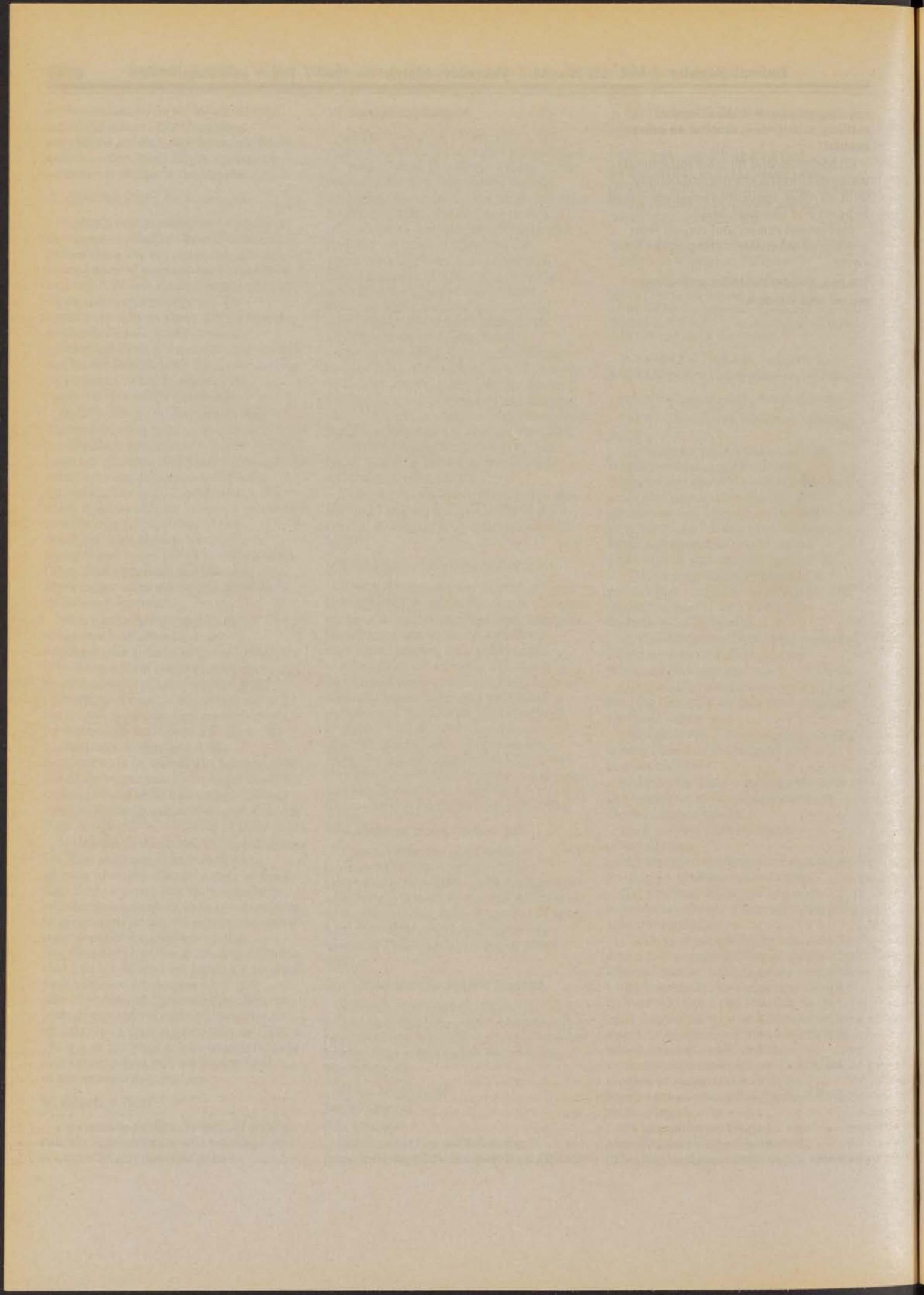
necessary to correct the effects of settling, subsidence, erosion, or other events;

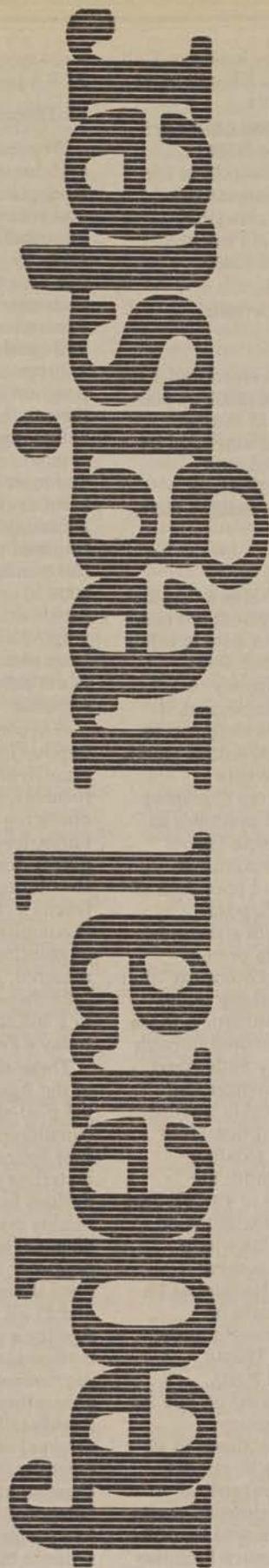
(2) Maintain and monitor the ground-water monitoring system and comply with all other applicable requirements of Subpart F of this part; and

(3) Prevent run-on and run-off from eroding or otherwise damaging the final cover.

[FR Doc. 87-5575 Filed 3-18-87; 8:45 am]

BILLING CODE 6560-50-M





Thursday
March 19, 1987

Part III

**Environmental
Protection Agency**

**40 CFR Parts 264, 265, and 270
Proposed Amendments for Landfill,
Surface Impoundment, and Waste Pile
Closures; Proposed Amendment to Rule**

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 264, 265, and 270**

[ISW-FRL-3092-2]

Proposed Amendments for Landfill, Surface Impoundment, and Waste Pile Closures; Proposed Rule**AGENCY:** U.S. Environmental Protection Agency (EPA).**ACTION:** Proposed Amendment to rule.

SUMMARY: The Agency is proposing to supplement the currently authorized options found in 40 CFR Parts 264 and 265 for closing and providing post-closure care for landfills, surface impoundments, and waste piles that are used to treat, store, or dispose of hazardous wastes. Under the supplemental option proposed today, the Agency and authorized States may establish appropriate closure and post-closure requirements on a site-specific basis. The requirements would be established by analyzing detailed data concerning the waste and site characteristics, and assessing all potential pathways by which hazardous constituents may migrate and pose threats to human health and the environment. The public will be provided an opportunity to comment fully in permit hearings on the appropriateness of the site-specific closure and post-closure requirements for individual facilities before they are made final.

The purpose of this proposed regulatory amendment is to allow increased technical flexibility for situations not adequately addressed by the broad nationwide closure standards now in effect. However, as with the existing standards, any alternative requirements established under the proposed regulatory amendments must be designed to protect human health and the environment.

DATE: Written comments should be submitted on or before May 18, 1987. An original and two copies of your comments on this proposal should be mailed to the Docket Clerk, Office of Solid Waste (WH-562), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460 and should be identified as follows: F-87-ACP-FFFFF.

ADDRESS: The official docket for this regulation including comments received by the Agency is located in Room MLG100, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, and is available for viewing from 9:00 a.m. to 3:30 p.m., Monday

through Friday, excluding holidays. Call Mia Zmud at 475-9327 or Kate Blow at 382-4675 for appointments.

FOR FURTHER INFORMATION CONTACT:

RCRA Hotline at 800-424-9346 (in Washington, DC, call 382-3000) or for technical information contact Ossi Meyn, Office of Solid Waste (WH-565E), U.S. Environmental Protection Agency, Washington, DC 20460, telephone (202) 382-4654.

SUPPLEMENTARY INFORMATION:**I. Authority**

These regulations are issued under the authority of sections 1006, 2002(a), 3004, 3005, and 3007 of the Solid Waste Disposal Act (SWDA), as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended (42 U.S.C. 6905, 6912(a), 6924, and 6925).

II. Background

Subtitle C of RCRA creates a "cradle-to-grave" management system intended to ensure that hazardous waste is safely treated, stored, or disposed. First, Subtitle C requires the Agency to identify hazardous waste. Second, it creates a manifest system designed to track the movement of hazardous waste, and requires hazardous waste generators and transporters to employ appropriate management practices as well as procedures to ensure the effective operation of the manifest system. Third, owners and operators of treatment, storage, and disposal facilities must comply with standards that "may be necessary to protect human health and the environment" that are established by the Agency under section 3004 of RCRA. Ultimately, these standards will be implemented through permits that are issued by authorized States or the Agency to owners and operators of hazardous waste treatment, storage, and disposal facilities. Until these permits are issued, existing facilities are controlled under the interim status regulations of 40 CFR Part 265 that were largely promulgated on May 19, 1980. Interim status waste facilities are waste management facilities in existence on November 19, 1980 (or on the effective date of statutory or regulatory changes under the Hazardous and Solid Waste Amendments (HSWA) of 1984).

In regulations promulgated on July 26, 1982 [47 FR 32274], the Agency established permitting standards in 40 CFR Part 264 covering the treatment, storage, and disposal of hazardous wastes in surface impoundments, waste piles, land treatment units, and landfills. Owners and operators of such facilities

must meet these standards to receive a RCRA permit.

III. Discussion of Today's Amendments

At present, the regulations afford one, and, for some units, two options for closing landfills, surface impoundments, and waste piles. In the case of surface impound and landfill units, one may close by placing a highly impermeable cap over the unit (and in the case of a surface impoundment, the unit must be dewatered and the wastes stabilized) and conducting a 30-year (or other appropriate period) post-closure program of monitoring and maintaining the cap; monitoring, maintaining, collecting and removing liquids in the leachate collection system if present; and monitoring the ground water. Where monitoring data indicates ground-water contamination, corrective action may be required pursuant to Part 264 Subpart F (for permitted facilities) or section 3008(h) of HSWA (for interim status facilities). This option is available to waste piles only after all wastes have been removed or decontaminated and it is not practical to remove contaminated subsoils.

A second option, available to surface impoundments and waste piles, is to remove or decontaminate all waste residues, contaminated design and operating system components (e.g. liners, leachate collection systems, and dikes), contaminated subsoils, and structures contaminated with waste and leachate. If this is successfully accomplished, no post-closure monitoring or other post-closure care is required. This type of closure is more fully discussed in the final amendments to § 265.228 published elsewhere in today's Federal Register.

These two closure options evolve out of the Agency's approach for minimizing the post-closure release of hazardous constituents into the environment. The first option, leaving waste in place but installing a low permeability cap, derives from the Agency's overall liquids management strategy for land disposal units. As described in the preamble to the minimum technology regulations (47 FR 32274, July 26, 1982 and 51 FR 10706, March 28, 1986), the Agency's general strategy for such units is to impose design and operational requirements to minimize leachate generation (e.g., caps and prohibition on liquids in landfills) and then to require removal of the leachate before liquids can migrate into the environment. Consistent with this control strategy, the "disposal" closure option requires very low permeability caps at closure in order to minimize post-closure

infiltration of liquid through the unit and the need for post-closure monitoring and corrective action.

The second closure option, closure by removal, eliminates the potential for leachate production after closure by removing the source of contamination. The goal at closure is to remove or decontaminate all materials on site that could potentially contribute to future contamination problems.

While each closure option adopts a different strategy to achieve protection of human health and the environment, the goal of both closure as a disposal unit and closure by removal is to minimize or eliminate potential threats to human health and the environment and the need for future corrective action at the site.

The Agency now has several years of experience in reviewing and approving closure plans under RCRA. Moreover, the Agency has gained considerable experience in effecting remedial actions under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) that are in many ways analogous to RCRA closures. Based on this experience, EPA believes that in many circumstances a "hybrid" approach that combines the strategies of closure by removal and closure as a disposal unit may be equally or more effective than either the pure "disposal" or "removal" closure option. Rather than designing all caps to minimize infiltration and allowing the waste to remain in place, this "hybrid" approach would consist of the removal of the majority of contaminated materials and would allow covers and post-closure monitoring to be designed based on the exposure pathway of concern. For example, if the constituents remaining in the soil were highly immobile and would not migrate to the ground water, the cover could be designed to prevent direct contact and inhalation of constituents (the pathways of concern), rather than to minimize infiltration. This allows the method of closure to be tailored to the specific circumstances under which the unit is being closed. It also creates an incentive to remove waste from the unit rather than leaving waste in place and relying on control strategies such as capping to minimize migration of constituents.

A few examples may help to explain how closure requirements may be altered to suit the site-specific conditions of the unit undergoing closure. Generally, situations in which alternate closure requirements may be appropriate are when: (1) Substantial removal of waste and waste residues will occur (but some minimal residual contamination is left in the unit); (2)

residual contamination has low mobility and toxicity; (3) pathways of potential exposures to contaminants are limited; and (4) long-term monitoring/care will be provided. The following examples should not be interpreted as scenarios that will in all cases qualify for the alternate closure requirements nor the only possible scenarios. However, these examples illustrate the point that site-specific conditions may in some cases call for site-specific closure requirements.

The following is an example of a closing unit, located in an arid region where infiltration is very low and evapotranspiration significantly exceeds precipitation, for which site-specific requirements are appropriate. The unit contains residual levels of relatively immobile contaminants; conservative estimates of attenuation of residual contaminants in the unsaturated zone show that the waste constituents will never migrate to the ground water, which is 100 feet below the unit. The owner or operator is able to show, based on waste and site conditions, that the residual wastes pose no surface water or atmospheric threat, and that direct contact with the waste is the only potential exposure pathway of concern. In this situation, a cover designed to prevent infiltration would be unnecessary, but a cover designed to protect against the direct contact threat would be required to fully protect human health and the environment at this site.

Indeed, the Agency has already acknowledged through rulemaking that a unit existing in such an environment may warrant reduced requirements. Such a unit is eligible for an exemption under § 264.90(b)(4) and § 264.221(b) from the ground-water monitoring requirements and single-liner requirements for surface impoundments if an owner or operator can demonstrate that no potential migration of liquid from the unit into ground water is possible during the active life and post-closure care period. The minimum technology requirements in the 1984 amendments to the Solid Waste Disposal Act allow for a similar waiver in section 3004(o)(2) from the statutory requirements. A unit in a low precipitation, high evapotranspiration environment with a deep water table may well be able to make such a demonstration of no migration.

Another situation that may warrant specific consideration is where an owner or operator may have removed all wastes and liner systems from a unit but residual waste constituents still remain in the unsaturated soil. If the waste constituents in the unsaturated

soil exceed Agency established health and environmental effect levels, then the unit may not meet the closure by removal test in §§ 264.228 and 265.228. (See the discussion of the "remove or decontaminate" standard in the preamble to § 265.228 elsewhere in today's *Federal Register*). However, when these residual concentrations are sufficiently low, fate and transport calculations based on waste constituent characteristics and site hydrogeologic and locational conditions may show that the waste residuals in the unsaturated soils will never produce ground-water contamination above an Agency established exposure level (see discussion below for explanation of Agency-established exposure levels). Since in this example the ground water will remain potable, the cap design for the unit does not have to prevent infiltration. Furthermore, if the owner or operator can show that the waste residuals pose no atmospheric, surface water, direct contact, or ingestion threat, then capping the unit may not be necessary to protect human health and the environment from the residual contamination. However, ground-water, vadose zone or soil monitoring is generally necessary to confirm or verify the fate and transport predictions.

Today's proposal specifies a set of factors that the Regional Administrator (or State) must consider when establishing alternate closure requirements under §§ 264.310(c) and 265.310(c). The Agency expects to limit the use of the alternate closure option to situations where residual hazardous constituents are present in low concentrations, are of low toxicity, and have low mobilities, where migration of the waste residuals to any medium is unlikely, and where long-term monitoring is guaranteed. The factors used in the Regional Administrator's analysis are designed to ensure that wastes and waste residues will not pose a threat to human health and the environment through any potential exposure pathway. These potential pathways include exposure to the waste constituents through direct contact, ground water, surface water, and atmospheric routes. Basically, the following topics must be examined: (1) The potential for the waste or waste constituents to migrate from the closing unit, (2) the toxicity of the waste or waste constituents that migrate from the unit, (3) the health and environmental effects associated with potential exposure to the waste or waste constituents that migrate from the unit, and (4) the uncertainty in each of the above analyses.

The factors the Regional Administrator would consider when establishing alternative closure requirements under §§ 264.310(c) and 265.310(c) are similar in many ways to factors the Regional Administrator considers when setting alternate concentration limits (ACLs) under § 264.94. The basic test of both of these alternate programs is the same: The alternate requirements must protect human health and the environment. The factors related to ground-water and surface-water impacts are the same for the alternate closure requirements as for the setting of ACLs. The main difference between the two procedures is that in the proposed closure demonstration the Regional Administrator may take into account attenuation in the unsaturated zone and may require different types of monitoring. In addition, where ACLs address only ground-water contamination, the proposed closure analysis would also address surface water and the potential exposure pathways of direct contact and atmospheric releases.

The closure demonstration submitted by facility owners and operators should rely on Agency-recommended exposure limits that have undergone peer review by the Agency. These include water quality standards and criteria (Ambient Water Quality Criteria: 45 FR 79318, November 28, 1980, 49 FR 5831, February 15, 1984; 50 FR 30784, July 29, 1985), health-based limits based on verified reference doses (RfDs) developed by the Agency's Risk Assessment Forum (Verified Reference Doses of USEPA, EACO-CIN-475, January 1986) and Carcinogenic Potency Factors (CPF) developed by the Agency's Carcinogen Assessment Group (Table-11, Health Assessment Document for Tetrachloroethylene (Perchloroethylene) USEPA, OHEA/6008-82/005F, July 1985), or site-specific Agency-reviewed public health evaluations, issued by the Agency for Toxic Substance and Disease Registry of the Center for Disease Control, Department of Health and Human Services.

The Agency is currently compiling toxicity information on many of the hazardous constituents contained in Appendix VIII of 40 CFR Part 261. The facility owners and operators should check with the Office of Solid Waste, Characterization and Assessment Division, Technical Assessment Branch (202) 382-4761 for the latest toxicity information. If no Agency-recommended exposure limits exist for a hazardous constituent then the facility owner or operator must either remove the constituent down to background levels,

submit data of sufficient quality for the Agency to determine the environmental and health effects of the constituent, or follow landfill closure and post-closure requirements. All data submitted by the owner or operator on environmental and health effects of a constituent should, when possible, follow the toxicity testing guidelines of 40 CFR Parts 797 and 798 (50 FR 39252, September 27, 1985). The Agency does not believe there are many situations where exposure limits will be developed by owners or operators, since testing required by 40 CFR Parts 797 and 798 to produce reliable toxicity estimates is an expensive and time-consuming effort.

For purposes of fate and transport modeling, it is necessary to identify points of exposure. In calculations that may be used to estimate the potential impacts of releases of hazardous constituents from closing units, points of exposure would be assumed as below. The points of exposure were chosen because the Agency believes that they are realistic and conservative estimates of where either environmental or human receptors would likely be exposed to the contaminants released from the unit. Furthermore, the Agency feels that they are conservative enough to be protective of human health and the environment in all situations that would be encountered during the alternate closure scenario. For closure under the proposed alternate requirements of §§ 264.310(c) and 265.310(c), the potential point of exposure for analysis of the direct contact and atmospheric routes is at or within the unit boundary. The potential point of exposure for surface water is at the edge of the closest on-site surface water runoff pathway (including ditches and intermittent streams) or actual surface water body that is affected by the unit. The potential point of exposure for ground water is the first aquifer found at the unit boundary. Generally the ground-water protection standard should be met in this first saturated zone at the unit boundary, if a cap and long-term management will be required. The ground-water protection standard should also be met at the first aquifer directly beneath the unit if no cap or long-term management will be required.

The Agency is soliciting comments on the concept of allowing the defined points of exposure to be moved beyond the unit boundary. For example in some situations, effective measurement of leakage may be better determined away from the unit. In such case, it may be equally protective to assume a point of exposure away from the unit boundary.

Comments are requested on the following points:

- (1) Under what conditions may the points of exposure be extended, and
- (2) What criteria must be met in specifying the extended points of exposure.

If any adjustments are made to the points of exposure, then long-term monitoring will be necessary to verify that no unacceptable levels of contaminants are migrating to or past the points of exposure.

The regulations require an owner or operator requesting approval of alternate site-specific closure requirements to submit site-specific supporting data. The data and data analysis submitted by the owner or operator must be of sufficient quality for the Regional Administrator to assess the factors for each of the exposure pathways listed in §§ 264.310(c) and 265.310(c). In addition, the following information must be submitted by the owner or operator: (1) A description of closure activities designed to meet the closure performance standard, (2) any data, models, and assumptions used to support fate and transport predictions, (3) design and operating plans of any proposed monitoring system used to verify fate and transport predictions, and (4) a plan which identifies subsequent contingency closure activities that may be needed if the alternate requirements are not successful and shows how these closure activities will be conducted. The specific information requirements are codified at §§ 265.310(c)(2) and 270.21(e)(2).

Any unit undergoing closure under the alternate requirements will need verification monitoring systems to confirm fate and transport predictions of hazardous constituents through any of the exposure pathways. Because of the uncertainties inherent in any form of modeling, the Agency plans to rely on monitoring to ensure that actual migration rates and concentrations of hazardous constituents are consistent with those projected as the basis of any alternate closure option. The verification monitoring may include, but is not limited to the following: (1) Leachate collection and analysis, (2) unsaturated zone monitoring, (3) air monitoring, (4) surface water runoff analysis, and (5) ground-water monitoring. For example, if the migration of hazardous constituents through the unsaturated zone is expected to be attenuated, then soil pore monitoring should be performed to verify this projection.

The Agency is asking for comments on whether to provide flexibility in specifying ground-water well locations (point of exposure for the ground-water pathway) for units that have

institutional or physical obstacles (e.g., buried pipelines, natural geologic features) which prevent the installation of downgradient monitoring wells directly at the unit boundary. Comments are requested on the criteria by which adjustments can be made to the placement of ground-water monitoring wells. The Agency believes that the distance the ground-water monitoring wells can be moved in order to avoid physical or institutional obstacles should be limited (perhaps to less than 50 feet) so that early detection of leakage from the unit could be detected.

The verification monitoring program for ground water may vary from the ground-water monitoring programs in §§ 264.97 and 264.100 in terms of well placement, sampling protocols, and duration (**Note:** § 264.117 already grants the Regional Administrator authority to modify the length of time that ground-water monitoring must be performed based on site-specific factors). The program, however, must be sufficient to verify the accuracy of fate and transport predictions and ensure that the alternate closure requirements are indeed meeting the closure performance standard. The Agency may, for example, require monitoring between the unit and the potential point of exposure to ensure that actual concentrations of constituents in air or water never exceed Agency approved levels or so that actual travel times of constituents can be compared with those predicted by the model. If observed constituent concentrations or migration rates differ from expected values, the Regional Administrator may invoke § 264.310(c)(3) or § 265.310(c)(3) to require further model validation, additional closure activities or ground-water corrective action to ensure compliance with the requirements of §§ 264.111 and 265.111.

Alternate closure requirements will not be established under § 265.310(c) on the basis that adverse effects on human health and the environment will simply be delayed for some period of time. Thus, the owner or operator would not be allowed to meet alternate closure requirements by arguing that a ground-water plume of contamination would not reach potential ground-water users (e.g., not migrate beyond the area of the unit or property boundary) for some period of time. The same concept applies for all the potential pathways for exposure; temporary prevention of adverse impacts is not grounds for alternate closure requirements under §§ 264.310(c) and 265.310(c).

The Agency believes that the alternative proposed in §§ 264.310(c)

and 265.310(c) generally will not be applicable to landfill and surface impoundment units closing with significant quantities of waste remaining in place. Under those circumstances, the possibility of a successful alternate closure is minimal since the potential for harm to human health and the environment posed by high concentrations of hazardous waste will be demonstrated by most valid fate and transport modeling processes. Likewise, facilities with units located in areas vulnerable to flooding and/or seismic activity will most likely be unable to make successful demonstrations for alternate closure requirements.

The Agency is soliciting comments on whether all wastes that were placed in the unit should be removed before an owner or operator can close under §§ 264.310(c) and 265.310(c). Could some wastes be allowed to remain in the unit if they are stabilized, have been treated, or if there are engineering controls (e.g., slurry walls)? Should geological characteristics, such as fractured bedrock or Karst topography be considered? In addition what location factors besides flooding and/or seismic activity should be assessed before allowing closure under the alternate approach?

The Agency is also requesting comments on how ground-water use should be considered in alternate closure considerations. The Agency is proposing to consider ground-water use when deciding on exposure assumptions for alternative closures (§§ 264.310(c)(i)(G) and 265.310(c)(i)(G)). For this purpose, ground water that is potentially potable, e.g. has less than 10,000 parts per million Total Dissolved Solids (TDS), will be considered to be a potential drinking water resource and drinking water exposure to possible contaminants will be considered. If the ground water is nonpotable (greater than 10,000 parts per million TDS), then drinking water exposure is unlikely and ground-water concerns may be secondary to other environmental exposures (direct contact, surface water, or atmospheric exposures).

The Agency is proposing to require closure approaches under §§ 264.310(c) and 265.310(c) to meet specific performance standards. The general closure performance standards of §§ 264.111 and 265.111 require the owner or operator to close the facility in a manner that: (1) Minimizes the need for further maintenance, and (2) controls, minimizes or eliminates, (to the extent necessary to prevent threats to human health and the environment), post-closure escape of hazardous waste,

hazardous waste constituents, leachate, contaminated rainfall, or waste decomposition products to the ground or surface waters or to the atmosphere. Today's proposed regulation includes more specific performance requirements for closure under §§ 264.310(c) and 265.310(c) to ensure that the site-specific closure requirements will be as effective in protecting human health and the environment as the final cover required by the closure option under §§ 264.310(b) and 265.310(b).

The owner or operator should submit a request for permit modification for an alternate closure at least one year before the expected closure date. He must then modify the closure and postclosure plan, filed with the permit application, to conform to the alternate set of closure and post-closure requirements, established by the Regional Administrator.

While the proposed rule allows an owner or operator to apply for approval of alternative closure one year before the expected closure date, the Agency is asking for comments on whether or not EPA should allow the owner or operator to request such a closure approach during the initial permit application stage. Because it may be difficult for an owner or operator to anticipate all of the waste and site factors that would be crucial in completing closure under the alternative approach, the Agency has chosen to require the approval of one of the two standard closure options (i.e., landfill closure or "clean closure") to assure that the intended closure is protective and supported by adequate financial responsibility. A modified closure plan, incorporating alternative closure could be submitted for Agency approval at the end of the operating period of the unit, when more definite information on waste and site factors would be available to the unit's owner or operator. The Agency is requesting comments on approval of alternative closure during the permitting process or prior to one year before the expected closure date. Commenters should address the Agency's concerns with respect to the uncertainties regarding alternative closure.

A final and very important area where the Agency seeks public comment is the issue of whether a unit should be allowed to close under the proposed alternative if hazardous constituents have already migrated to ground water above Agency approved levels. The Agency is presently considering four options for defining closure alternatives for units with existing ground-water contamination.

Option I: Units with ground-water contamination above Agency-approved levels would be considered ineligible for the alternate closure option and must instead close as a landfill.

Option II: Units where levels of constituents in ground water are above Agency approved levels would be considered eligible to close under § 264.310(c) or § 265.310(c) only if owners or operators undertake ground-water remediation during the closure period in order to meet Agency-approved levels.

Option III: Units with ground-water contamination would be allowed to close under § 264.310(c) or § 265.310(c) without immediately addressing ground-water contamination originating from that unit, but the facility would not be allowed to certify final *facility closure* until all ground-water contamination had been addressed.

Option IV: Units with ground-water contamination would be allowed to close under § 264.310(c) or § 265.310(c) but must conduct corrective action during the post-closure period.

The following paragraphs discuss each of these options.

Option I: No Contamination

The alternate closure option would only be available to units *without* ground-water contamination at the time of closure. Availability for the alternate closure under this option would be essentially the same as for "clean" closures under the existing regulations. However, in contrast to "clean" closures which require levels of constituents in the unsaturated zone to be below Agency-approved levels, Option I of the alternate closure rule would allow modeling through the unsaturated zone to show that levels of constituents unacceptable in the leachate would be attenuated to safe levels before reaching the ground water. As described elsewhere in today's *Federal Register*, the current regulations normally force units with ground-water contamination into the landfill option because contaminated ground water and soils cannot be completely excavated during the limited time allowed for closure.

A drawback to taking this approach is that there may be situations where capping an old unit (i.e., closing as a landfill) may provide no incremental environmental benefit even though there is an existing ground-water problem. For example, the mobile and toxic fractions of a waste may have already migrated away from the unit at the time of closure, or the owner or operator may be able to remove a sufficient volume of waste so that he can demonstrate that the level of contamination remaining in the soil will not contribute further to the existing ground-water problem. In such situations, the installation of an impervious cap may serve no useful

purpose in preventing further ground-water degradation and will not help clean up the existing problem. In fact, a cap may complicate or prohibit certain corrective actions by adding additional material that must be excavated or by interfering with a pump and treatment program that relies on "flushing" contaminants through the aquifer. Recognizing this, the Agency is also considering options II, III and IV below.

Option II: Clean up Ground Water To Meet Ground-Water Protection Standard

Under this option, units with ground-water contamination would have to meet Agency-approved health-based levels in the ground water before certifying closure under the alternate closure option [§§ 264.310(c) or 265.310(c)]. However, owners or operators would be allowed to undertake corrective action as a closure activity in order to meet the ground-water protection standard of § 264.92 in the ground water.

To make this option available, the Agency would have to amend Subpart G §§ 264.113(b) and 265.113(c) to authorize the Regional Administrator to extend the closure period in certain limited circumstances, including the need to incorporate long-term corrective action into the closure process. The drawback of this approach is that if corrective action were incorporated into the closure process, final closure certifications would be delayed (possibly for many years) because owners or operators would not be allowed to certify unit closure until any contamination emanating from that unit had been cleaned up. The benefit of this approach is assurance that ground-water problems are addressed without imposing costly requirements (such as impervious caps) in situations where they arguably provide no environmental benefit and may, in fact, impede corrective action.

Option III: Facility Closure Contingent on Ground-Water Clean-up.

In option III, *units with existing ground-water contamination* would be allowed to close under the alternate closure option without necessarily addressing the plume originating from that unit, but final *facility closure* would be dependent on addressing *all* ground-water problems at that site. In effect, this option would disassociate an owner or operator's responsibility to address soil contamination at a particular unit from his obligation to clean up ground water at his facility. Capping decisions for individual units would be based on direct contact and inhalation concerns

and the need to prevent additional contamination of ground water. If existing ground-water contamination warrants immediate attention, corrective action could be compelled through a section 3008(h) order, a post-closure permit, or appropriate State Authority. If, however, the contamination from the closing unit commingles with ground-water contamination from other units (and the plume is not posing an immediate threat), it may make more sense to address the ground-water problem as a whole rather than trying to address the individual contribution from each unit through separate actions. As with the landfill option, the owner or operator closing a unit under § 264.310(c) and § 265.310(c) would know that although the unit has been closed, they still have outstanding corrective action requirements. The owner or operator would remain subject to a facility-wide responsibility for future ground-water clean-up, not just responsibility for addressing the contribution from the individual closing unit.

Option IV: Clean up Ground Water During the Post-Closure Care Period.

This option would allow a unit to be closed under § 264.310(c) or § 265.310(c), although ground-water contamination was evident at the time of certification of closure. The owner or operator of the closed unit would be responsible for performing corrective action during the post-closure period to meet the ground-water protection standard of § 264.92. The post-closure permit would include provisions for performing corrective action, including identification of remedial methods, chemical constituents, target concentrations levels and ground-water monitoring. The owner or operator would continue to be responsible for meeting the requirements of § 264.117 or § 265.117. The advantage of the option would be to allow completion of all other closure activities (e.g., installation of a cover system), to begin all other post-closure-care activities (e.g., monitoring and maintaining the leachate collection, leak detection, and cover system), and complete all corrective action, which may involve a much longer period of time than was envisioned for routine closure activities. The rule as proposed today does not reflect any of the four options. Based on public comment, the Agency will select an approach and make modifications to the rule as proposed to make clear the Agency's position on how existing ground-water contamination will affect the specific closure options.

IV. State Authority

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA program within the State. (See 40 CFR Part 271 for the standards and requirements for authorization. Following authorization, the Agency retains enforcement authority under sections 3008, 7003 and 3013 of RCRA, although authorized States have primary enforcement responsibility.

Prior to the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The Federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in the State which the State was authorized to permit. When new, more stringent Federal requirements were promulgated or enacted, the State was obliged to enact equivalent authority within specified time frames. New Federal requirements did not take effect in an authorized State until the State adopted the requirements as State law.

In contrast, under section 3006(g) of RCRA, 42 U.S.C. 6926(g), new requirements and prohibitions imposed by the HSWA take effect in nonauthorized States. EPA is directed to carry out those requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA-related provisions as State law to retain final authorization, the HSWA applies in authorized States in the interim.

B. Effect on State Authorizations

Today's rule proposes standards that would not be effective in authorized States since the requirements would not be imposed pursuant to the Hazardous and Solid Waste Amendments of 1984. Thus, the requirements will be applicable only in those States that do not have interim or final authorization. In authorized States, the requirements will not be applicable until the States revises its program to adopt equivalent requirements under State law.

40 CFR 271.21(e)(2) requires that States that have final authorization must modify their programs to reflect Federal program changes and must subsequently submit the modifications to EPA for approval. [For proposals: The deadline by which the State must modify its

program to adopt this proposed regulation will be determined by the date of promulgation of the final rule in accordance with § 271.21(e). (Note to regulation writer: See attached chart to determine the appropriate date)]. These deadlines can be extended in certain cases (40 CFR 271.21(e)(3)). Once EPA approves the modification, the State requirements become Subtitle C RCRA requirements.

States with authorized RCRA programs may already have requirements similar to those in today's rule. These State regulations have not been assessed against the Federal regulations being proposed today to determine whether they meet the tests for authorization. Thus, a State is not authorized to carry out these requirements in lieu of EPA until the State program modification is submitted to EPA and approved. Of course, States with existing standards may continue to administer and enforce their standards as a matter of State law.

States that submit their official application for final authorization less than 12 months after the effective date of these standards are not required to include standards equivalent to these standards in their application. However, the State must modify its program by the deadlines set forth in § 271.21(e). States that submit official applications for final authorization 12 months after the effective date of those standards must include standards equivalent to these standards in their application. 40 CFR 271.3 sets forth the requirements a State must meet when submitting its final authorization application.

V. Regulatory Impact

Under Executive Order 12291, the Agency must determine whether a regulation is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. The Agency does not believe that these changes will result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or in domestic or export markets. In addition, the proposed changes allow another closure option which, in many cases, will be less expensive to implement than the existing standard. Therefore, the Agency believes that today's rule is not a major rule under Executive Order 12291.

This regulation was submitted to the Office of Management and Budget for

review as required by Executive Order 12291.

VI. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601, et seq.), the Agency must prepare a regulatory flexibility analysis for all regulations that may have a significant impact on a substantial number of small entities. The Agency conducted such an analysis on the land disposal regulations and published a summary of the results in the *Federal Register*, Vol. 48, No. 15, on January 21, 1983. The additional burdens imposed by this regulation are not significant. In fact, this regulation will likely reduce economic burden by allowing for another closure option.

VII. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. Submit comments on these requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), 726 Jackson Place, NW., Washington, DC 20503, marked "Attention: Desk Officer for EPA". The final rule will respond to any OMB or public comments on the information collection requirements.

List of Subjects

40 CFR Part 264

Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

40 CFR Part 265

Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

40 CFR Part 270

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Dated: March 8, 1987.

Lee M. Thomas,
Administrator.

Therefore, it is proposed that 40 CFR Chapter I be amended as follows:

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

1. The authority citation for Part 264 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3004, and 3005 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, as amended (42 U.S.C. 6905, 6912(a), 6924, and 6925).

2. In § 264.90 by adding paragraph (c)(4).

§ 264.90 Applicability.

(c) * * *

(4) May be modified or replaced by an alternate monitoring program, incorporated in an approved closure plan, designed to verify the adequacy of a closure undertaken pursuant to § 264.310(c).

3. In § 264.228 by removing paragraph (b) and redesignating paragraph (c) as paragraph (b) and revising paragraph (a)(2) to read as follows:

§ 264.228 Closure and post-closure care.

(a) * * *

(2)(i) Eliminate free liquids by removing liquid wastes and solidifying the remaining wastes and waste residues;

(ii) Stabilize remaining waste to a bearing capacity sufficient to support final cover; and

(iii) Comply with the requirements of § 264.310.

4. In § 264.310 by revising it to read as follows:

§ 264.310 Closure and post-closure care.

(a) At final closure of the landfill and upon closure of any cell, the owner or operator must perform closure and postclosure care in accordance with the requirements of either paragraph (b) or (c) of this section.

(b)(1) The owner or operator must cover the landfill or cell with a final cover designed and constructed to:

(i) Provide long-term minimization of migration of liquids through the closed landfill;

(ii) Function with minimum maintenance;

(iii) Promote drainage and minimize erosion or abrasion of the cover;

(iv) Accommodate settling and subsidence so that the cover's integrity is maintained; and

(v) Have a permeability less than or equal to the permeability of any bottom liner system or natural subsoils present.

(2) After final closure, the owner or operator must comply with all post-

closure requirements contained in §§ 264.117 through 264.120, including maintenance and monitoring throughout the post-closure care period (specified in the permit under § 264.117). The owner or operator must:

(i) Maintain the integrity and effectiveness of the final cover, including making repairs to the cap as necessary to correct the effects of settling, subsidence, erosion, or other events.

(ii) Continue to operate the leachate collection and removal system until leachate is no longer detected;

(iii) Maintain and monitor the ground-water monitoring system and comply with all other applicable requirements of Subpart F of this part;

(iv) Prevent run-on and run-off from eroding and otherwise damaging the final cover; and

(v) Protect and maintain surveyed benchmarks used in complying with § 264.309, or

(c) The owner or operator must comply with an alternate set of closure and post-closure requirements that are established by the Regional Administrator by modifying the permit at the time of closure and that are specific to the unit being closed.

The Regional Administrator shall authorize alternate requirements under this paragraph only if he or she finds, based upon consideration of the factors set forth in paragraph (c)(1) of this section and the data submitted by the owner or operator under paragraph(c)(2) of this section, that the requirements will assure the achievement of the closure performance standard in § 264.111 and will be at least as effective in protecting human health and the environment as the final cover required under paragraph (b) of this section. These requirements shall include, an appropriate closure/post-closure verification monitoring program for exposure pathways of concern at the site. This monitoring program must be sufficient to verify the accuracy of any fate and transport calculations used in the design of the closure system being proposed.

(1) In determining whether to authorize alternate closure requirements under this paragraph the Regional Administrator will consider the following factors:

(i) Potential adverse effects on ground-water quality, considering:

(A) The physical and chemical characteristics of the waste in the unit(s) to be closed, including its toxicity and bioaccumulation potential and its mobility and persistence.

(B) The hydrogeological characteristics of the facility and surrounding land;

(C) The characteristics of the unsaturated zone that may affect the fate and transport of waste constituents from the unit(s) to be closed;

(D) The direction and rate of ground-water flow;

(E) The proximity and withdrawal rates of ground-water users;

(F) The current and future uses of ground water in the area;

(G) The existing quality of ground water, including other sources of contamination and their cumulative impact on the ground-water quality;

(H) The potential for health risks caused by human exposure to waste constituents;

(I) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents;

(J) The persistence and permanence of the potential adverse effects; and

(ii) Potential adverse effects on surface water quality, considering:

(A) The physical and chemical characteristics of the waste and waste constituents in the unit(s) to be closed; including its toxicity and bioaccumulation potential and its mobility and persistence.

(B) The topographic characteristics of the facility and surrounding land, including run-off and run-on patterns;

(C) The quality of ground-water and the direction of ground-water flow;

(D) The patterns of precipitation and evapotranspiration of the region;

(E) The proximity of the unit(s) to be closed to surface waters;

(F) The current and future uses of surface waters in the area and any water quality standards established for those surface waters;

(G) The existing quality of surface water, including other sources of contamination and the cumulative impact on surface water quality;

(H) The potential for health risks caused by human exposure to waste constituents;

(I) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents; and

(J) The persistence and permanence of the potential adverse effects, and

(iii) Potential adverse effects caused by direct contact to the waste and waste constituents considering:

(A) The physical and chemical characteristics of the waste and waste constituents in the unit(s) to be closed; including its toxicity and

bioaccumulation potential and its mobility and persistence.

(B) The current and future uses of the area;

(C) The potential for human exposure to waste constituents;

(D) The potential for health risks caused by exposure to waste constituents;

(E) The potential damage to wildlife, crop vegetation, and physical structures caused by exposure to waste constituents;

(F) The persistence and permanence of the potential adverse effects; and

(iv) Potential adverse effects caused by release to the atmosphere of waste or waste constituents considering:

(A) The physical and chemical characteristics of the waste and waste constituents in the unit(s) to be closed; including its toxicity and bioaccumulation potential and its mobility and persistence.

(B) The current and future uses of the area;

(C) The potential for human exposure to waste constituents;

(D) The potential for health risks caused by exposure to waste constituents;

(E) The potential damage to wildlife, crop vegetation, and physical structures caused by exposure to waste constituents;

(F) The persistence and permanence of the potential adverse effects.

(v) The engineered characteristics of the unit(s) to be closed that affect ground-water, surface water, direct contact, or atmospheric exposure pathways.

(2) An owner or operator submitting closure and post-closure plans to conduct closure and post-closure care under this paragraph must submit data that is of sufficient quality for the Regional Administrator to assess the factors listed in subparagraph (1) of this paragraph. At a minimum, the information required by § 270.21(e)(2) must be submitted to the Regional Administrator.

(3) If, at any time during the post-closure care period, the Regional Administrator determines that any of the assumptions underlying fate and transport calculations used to justify the closure systems are incorrect or that the alternate requirements have not ensured compliance with § 264.111, the Regional Administrator may impose such additional requirements, including those set forth in paragraph (b) of this section, as may be necessary to ensure compliance with § 264.111.

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

5. The authority citation for Part 265 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3004, 3005, and 3015, Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, as amended (42 U.S.C. 6905, 6912(a), 6924, 6925, and 6935).

6. In § 265.90 by adding paragraph (c)(3).

§ 265.90 Applicability.

(c) * * *
 (3) May be modified or replaced by an alternate ground-water monitoring program, incorporated in an approved closure plan, designed to verify the adequacy of a closure undertaken pursuant to § 265.310(c).
 * * * * *

7. In § 265.228 by removing paragraph (b) and designating paragraph (c) as paragraph (b) and revising paragraphs (a)(2) to read as follows:

§ 265.228 Closure and post-closure.

(a) * * *

(2)(i) Eliminate free liquids by receiving liquids wastes or solidifying the remaining wastes and waste residues;

(ii) Stabilize remaining waste to a bearing capacity sufficient to support final cover; and

(iii) comply with requirements of § 265.310.
 * * * * *

8. In § 265.310 by revising it to read as follows:

§ 265.310 Closure and post-closure care.

(a) At final closure of the landfill or upon closure of any cell, the owner or operator must perform closure and post-closure care in accordance with the requirements or either paragraphs (b) or (c) of this section.

(b)(1) The owner or operator must cover the landfill or cell with a final cover designed and constructed to:

(i) Provide long-term minimization of migration of liquids through the closed landfill;

(ii) Function with minimum maintenance;

(iii) Promote drainage and minimize erosion or abrasion of the cover;

(iv) Accommodate settling and subsidence so that the cover's integrity is maintained; and

(v) Have a permeability less than or equal to the permeability of any bottom liner system or natural subsoils present.

(2) After final closure, the owner or operator must comply with all post-closure requirements contained in §§ 265.117 through 265.120, including maintenance and monitoring throughout the post-closure care period. The owner or operator must:

(i) Maintain the integrity and effectiveness of the final cover, including making repairs to the cap as necessary to correct the effects of settling, subsidence, erosion, or other events.

(ii) Maintain and monitor the ground-water monitoring system and comply with all other applicable requirements of Subpart F of this part;

(iii) Prevent run-on and run-off from eroding or otherwise damaging the final cover; and

(iv) Protect and maintain surveyed benchmarks used in complying with § 265.309, or

(c) The owner or operator must comply with an alternate set of closure and post-closure requirements that are established by the Regional Administrator at the time of closure and that are specific to the unit being closed. The Regional Administrator shall authorize alternate requirements under this paragraph only if he or she finds, based upon considerations of factors set forth in paragraph (c)(1) of this section and the data submitted by the owner or operator under paragraph (c)(2) of this section, that the requirements will assure the achievement of the closure performance standard in § 265.111 and will be at least as effective in protecting human health and the environment as the final cover required under paragraph (b) of this section. These requirements shall include, an appropriate closure/postclosure verification monitoring program for exposure pathways of concern at the site. This monitoring program must be sufficient to verify the accuracy of any fate and transport calculations used in the design of the closure system being proposed.

(1) In determining whether to authorize alternate closure requirements under this paragraph the Regional Administrator will consider the following factors:

(i) Potential adverse effects on ground-water quality, considering:

(A) The physical and chemical characteristics of the waste in the unit(s) to be closed, including its toxicity and bioaccumulation potential and its mobility and persistence.

(B) The hydrogeological characteristics of the facility and surrounding land;

(C) The characteristics of the unsaturated zone that may affect the

fate and transport of waste constituents from the unit(s) to be closed.

(D) The direction and rate of ground-water flow;

(E) The proximity and withdrawal rates of ground-water users;

(F) The current and future uses of ground water in the area;

(G) The existing quality of ground water, including other sources of contamination and their cumulative impact on the ground-water quality;

(H) The potential for health risks caused by human exposure to waste constituents;

(I) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents;

(J) The persistence and permanence of the potential adverse effects; and

(ii) Potential adverse effects on surface water quality, considering:

(A) The physical and chemical characteristics of the waste and waste constituents in the unit(s) to be closed; including its toxicity and bioaccumulation potential and its mobility and persistence.

(B) The topographic characteristics of the facility and surrounding land, including runoff and runoff patterns;

(C) The quality of ground-water and the direction of ground-water flow;

(D) The patterns of precipitation and evapotranspiration of the region;

(E) The proximity of the unit(s) to be closed to surface waters;

(F) The current and future uses of surface waters in the area and any water quality standards established for those surface waters;

(G) The existing quality of surface water, including other sources of contamination and the cumulative impact on surface water quality;

(H) The potential for health risks caused by human exposure to waste constituents;

(I) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents; and

(J) The persistence and permanence of the potential adverse effects, and

(iii) Potential adverse effects caused by direct contact to the waste and waste constituents considering:

(A) The physical and chemical characteristics of the waste and waste constituents in the unit(s) to be closed; including its toxicity and bioaccumulation potential and its mobility and persistence.

(B) The current and future uses of the area;

(C) The potential for human exposure to waste constituents;

(D) The potential for health risks caused by exposure to waste constituents;

(E) The potential damage to wildlife, crop vegetation, and physical structures caused by exposure to waste constituents;

(F) The persistence and permanence of the potential adverse effects; and

(iv) Potential adverse effects caused by release to the atmosphere of waste or waste constituents considering:

(A) The physical and chemical characteristics of the waste and waste constituents in the unit(s) to be closed; including its toxicity and bioaccumulation potential and its mobility and persistence.

(B) The current and future uses of the area;

(C) The potential for human exposure to waste constituents;

(D) The potential for health risks caused by exposure to waste constituents;

(E) The potential damage to wildlife, crop vegetation, and physical structures caused by exposure to waste constituents.

(F) The persistence and permanence of the potential adverse effects.

(v) The engineered characteristics of the unit(s) to be closed that affect ground water, surface water, direct contact, or atmospheric exposure pathways.

(2) An owner or operator submitting closure and post-closure plans to conduct closure and post-closure care under this paragraph must submit data that is of sufficient quality for the Regional Administrator to assess the factors listed in paragraph (c)(1) of this section. At a minimum, the following information must be submitted to the Regional Administrator:

(i) A description of all closure activities proposed to meet the closure performance standard of § 265.111 including:

(A) Detailed design and construction plans for any proposed cover;

(B) Methods for any proposed removal, treatment, or immobilization of waste, waste residues, surrounding and underlying contaminated soil and/or ground water necessary to meet the closure performance standard in § 265.111;

(C) Sampling methods to verify the levels of constituents remaining in waste residue, soil, and/or ground water after any proposed removal and a schedule for submitting these data to the Administrator; and

(D) Design plans for any proposed engineered barriers.

(ii) A proposed modeling approach, where required, for predicting the fate

and concentration of hazardous constituents or waste degradation products at the point(s) of exposure. The model(s) used must be appropriate for simulating the environmental conditions at the site. Data and documentation to support any fate and transport predictions must include but not be limited to:

(A) The physical and chemical characteristics of the waste or waste residue including the maximum concentration and characteristics of each Appendix VIII constituent that could reasonably be derived from the original waste(s) placed in the unit(s);

(B) The concentration of Appendix VIII constituents that could be expected in leachate produced by the remaining waste, waste residue, and/or contaminated soil;

(C) Estimated quantity of waste residue and contaminated soil expected to remain on site;

(D) Hydrogeologic properties of the saturated and unsaturated zone that may affect the fate and transport of hazardous constituents;

(E) A method and justification for any proposed grouping of constituents for the purpose of fate and transport analysis;

(F) An evaluation of the performance of any engineered components of the unit or any proposed closure activities and an explanation of how these control strategies figure into fate and transport predictions;

(G) The capabilities, assumptions, and limitations of any proposed model(s) including rationales for selected input criteria, methods and QA/QC for obtaining necessary data, and a comparison of the model's assumptions to actual site characteristics; and

(H) The concentration in ground water of all Appendix VIII constituents that could reasonably be derived from the waste.

(iii) Design and operating plans for a proposed monitoring system to verify the accuracy of any fate and transport predictions, including:

(A) A proposed period of operation; and

(B) Levels in each medium of concern that will prompt notifications of the Regional Administrator.

(iv) A topographic map showing a distance of 1000 feet around the facility at scale of 2.5 centimeters (1 inch) equal to not more than 61.0 meters (200 feet). Contours must be shown on the map. The contour interval must be sufficient to clearly show the pattern of surface water flow in the vicinity of and from each operational unit of the facility (for example, contours with an interval of 1.5

meters (5 feet), if relief is greater than 6.1 meters (20 feet), or an interval of 0.6 meters (2 feet), if relief is less than 6.1 meters (20 feet)). Owners and operators of HWM facilities located in mountainous areas should use large contour intervals to adequately show topographic profiles of facilities. The map shall clearly show the following:

- (A) Map scale and date;
 - (B) 100-year floodplain area;
 - (C) Surface waters including intermittent streams;
 - (D) Surrounding land uses (residential, commercial, agricultural, recreational);
 - (E) A wind rose (i.e., prevailing windspeed and direction);
 - (F) Orientation of the map (north arrow);
 - (G) Legal boundaries of the HWM facility site;
 - (H) Access control (fences, gates);
 - (I) Injection and withdrawal wells both on-site and off-site;
 - (J) Buildings; treatment, storage, or disposal operations; or other structure (recreation areas, runoff control systems, access and internal roads, storm, sanitary, and process sewerage systems, loading and unloading areas, fire control facilities, etc.);
 - (K) Barriers for drainage or flood control;
 - (L) Location of operational and closed units within the HWM facility site, where hazardous waste is or was treated, stored, or disposed (include equipment cleanup areas); and
 - (M) Location of faults and other geologic seismic zones.
- (3) If, at any time during the post-closure care period, the Regional Administrator determines that any of the assumptions underlying fate and transport calculations used to justify the closure systems are incorrect or the alternate requirements have not ensured compliance with § 265.111, the Regional Administrator may impose such additional requirements including those set forth in paragraph (b) of this section as may be necessary to ensure compliance with § 265.111.

PART 270—EPA-ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

9. The authority citation for Part 270 is revised to read as follows:

Authority: Secs. 1006, 2002, 3004, 3005, 3007, 3019, and 7004. Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974).

10. § 270.17 is amended by revising paragraph (g) to read as follows:

- § 270.17 Specific Part B information requirements for surface impoundments.**
- * * *
- (g) A description of how hazardous waste residues and contaminated materials will be removed from the unit at closure, as required under § 264.228(a)(1). For any wastes not to be removed from the unit upon closure, the owner or operator must submit detailed plans and an engineering report describing compliance with § 264.310(b). This information should be included in the closure plan and, where applicable, the post-closure plan submitted under § 270.14(b)(13). The owner or operator may apply at the time of closure for alternate closure requirements under § 264.310(c) by requesting a permit modification and submitting the information required in § 270.21(e)(2).
- * * *
11. § 270.18 is amended by revising paragraph (h) to read as follows:
- § 270.18 Specific Part B information requirements for waste piles.**
- * * *
- (h) A description of how hazardous waste residues and contaminated materials will be removed from the waste pile at closure, as required under § 264.258(a). For any waste not to be removed from the waste pile upon closure, the owner or operator must submit detailed plans and an engineering report describing compliance with § 264.310(b). This information should be included in the closure plan and, where applicable, the post-closure plan submitted under § 270.14(b)(13). The owner or operator may apply at the time of closure for alternate closure requirements under § 264.310(c) by requesting a permit modification and submitting the information required in § 270.21(e)(2).

12. In § 270.21 by revising paragraph (e) to read as follows:

§ 270.21 Specific Part B information requirements for landfills.

* * *

- (e)(1) Detailed plans and an engineering report describing the final cover which will be applied to each landfill or landfill cell at closure in accordance with § 264.310(b)(1), and a description of how each landfill will be maintained and monitored after closure in accordance with § 264.310(b)(2). This information should be included in the closure and post-closure plans submitted under § 270.14(b)(13).

(2) For owners and operators requesting permit modifications at the time of closure to perform closure and post-closure care under § 264.310(c), the following additional information:

(i) A description of all closure activities proposed to meet the closure performance standard of § 264.111 including:

(A) Detailed design and construction plans for any proposed cover;

(B) Methods for any proposed removal, treatment, or immobilization of waste, waste residues, surrounding and underlying contaminated soil and/or ground water necessary to meet the closure performance standard in § 264.111;

(C) Sampling methods to verify the levels of constituents remaining in waste residue, soil, and/or ground-water after any proposed removal and a schedule for submitting these data to the Administrator; and

(D) Design plans for any proposed engineered barriers.

(ii) A proposed modeling approach for predicting the fate and concentration of hazardous constituents or waste degradation products at the point(s) of exposure. The model(s) used must be appropriate for simulating the environmental conditions at the site. Data and documentation to support any fate and transport predictions must include but not be limited to:

(A) The physical and chemical characteristics of the waste or waste residue including the maximum concentration and characteristics of each Appendix VIII constituent that could reasonably be derived from the original waste(s) placed in the unit(s);

(B) The concentration of Appendix VIII constituents that could be expected in leachate produced by the remaining waste, waste residue, and/or contaminated soil;

(C) Estimated quantity of waste residue and contaminated soil expected to remain on site;

(D) Hydrogeologic properties of the saturated and unsaturated zone that may affect the fate and transport of hazardous constituents;

(E) A method and justification for any proposed grouping of constituents for the purpose of fate and transport analysis;

(F) An evaluation of the performance of any engineered components of the unit or any proposed closure activities and an explanation of how these control strategies figure into fate and transport predictions;

(G) The capabilities, assumptions, and limitations of any proposed model(s) including rationales for selected input criteria, methods and QA/QC for obtaining necessary data, and a comparison of the model's assumptions to actual site characteristics; and

(H) The concentration in groundwater of all Appendix VIII constituents that could reasonably be derived from the waste.

(iii) Design and operating plans for a proposed monitoring system to verify the accuracy of any fate and transport predictions, including:

(A) A proposed period of operation; and

(B) Contaminant levels in each medium of concern that will prompt notification of the Regional Administrator.

Note.—The following information, relevant to evaluating closure demonstrations under § 264.310(c), is required elsewhere in Part 270:

General facility location and design information as required in § 270.14(b)(11) and § 270.14(b)(19);

Description of any plume of contamination including the maximum concentration of all Appendix VIII constituents.

* * * * *

13. In § 270.41 by revising paragraph (a)(5)(i) to read as follows:

§ 270.41 Major modification or revocation and reissuance of permits.

(a) * * *

(5) * * *

(i) When modification of a closure plan is required under § 264.112(b) or § 264.118(b), or when an owner or operator requests authorization to perform closure and post-closure care under § 264.310(c).

* * * * *

[FR Doc. 87-5576 Filed 3-18-87; 8:45 am]

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U.S. Environmental Protection Agency

Thursday
March 19, 1987

Part IV

**Environmental
Protection Agency**

40 CFR Part 61

**National Emission Standards for
Hazardous Air Pollutants; Review and
Revision of the Standards for Mercury;
Final Rule; Review**

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 61**

[AD-FRL-3072-7]

National Emission Standards for Hazardous Air Pollutants; Review and Revision of the Standards for Mercury**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final Rule; Review.

SUMMARY: Today's action promulgates revisions to the national emission standards for the hazardous air pollutant mercury [Chemical Abstract Service (CAS) Registry Number 7439-97-6]. Revisions were proposed in the *Federal Register* on December 26, 1984. These revisions add monitoring, reporting, and one-time emission testing requirements to the standards for mercury-cell chlor-alkali plants and allow an owner or operator the option of developing and submitting for approval a plant-specific monitoring plan. The revisions also allow the owner or operator of any facility affected by 40 CFR Part 61, Subpart E, up to 15 days to verify the validity of source test data prior to reporting the results to the Administrator.

EFFECTIVE DATE: March 19, 1987. These revisions become effective upon promulgation and apply to all new and existing affected facilities.

Under section 307(b)(1) of the Clean Air Act, judicial review of the actions taken by this notice is available *only* by the filing of a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit within 80 days of today's publication. Under section 307(b)(2) of the Clean Air Act, the requirements that are the subject of today's notice may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

ADDRESSES: *Review Documents.* The document summarizing emissions information gathered during the review of the standards may be obtained from the EPA Library (MD-35), Research Triangle Park, North Carolina 27711, telephone number (919) 541-2777. Please refer to "Review of National Emission Standards for Mercury," EPA-450/3-84-014b.

The document summarizing current information on the potential health effects associated with mercury exposures may be obtained from the National Technical Information Service, U.S. Department of Commerce, Springfield, Virginia 22161, telephone

number (703) 487-4650 (NTIS stock number PB-85-123925). Refer to "Mercury Health Effects Update," EPA-600/8-84-019F, August 1984. The price of the document, including shipping, is \$19.95.

Docket. Docket No. A-82-41, containing information considered by EPA in developing the revisions, is available for public inspection and copying between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section, West Tower Lobby, Gallery 1, Waterside Mall, 401 M Street, SW., Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT:

Policy issues: Ms. Dianne Byrne or Mr. Gil Wood, Standards Development Branch, Emission Standards and Engineering Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5578

Technical issues: Mr. John Copeland or Dr. James Crowder, Industrial Studies Branch, Emission Standards and Engineering Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5601.

SUPPLEMENTARY INFORMATION:**I. Summary of Review and Revisions**

The national emission standards for mercury limit emissions from mercury ore processing facilities, sludge incineration and drying plants, and mercury-cell chlor-alkali plants. During its review of the standards, the EPA identified two areas in which revisions were warranted. The first area pertains to the appropriate amount of time, following completion of performance tests, that should be provided for reporting the results of those tests to the Administrator. The standards allowed 30 days following completion of the performance tests for the samples to be analyzed and emissions to be determined and required that the results be reported on the day after the determination was made. These revisions change that requirement. An owner or operator is now allowed 15 days after the determination of emissions to notify the Administrator of the test results. The additional 2 weeks are to provide time for the results to be reviewed and verified at the source before they are sent to the Administrator.

The second area in which revisions to the standards were warranted pertains to the monitoring and recordkeeping requirements for chlor-alkali plants. Compliance data for the hydrogen and

chlorine ventilation streams at mercury-cell chlor-alkali plants indicated that, while many plants emit at levels just below the standard during normal operations, excess emissions have occurred during periods of control systems failures. To ensure that control systems are properly operated and maintained on a continuous basis, specific monitoring, recordkeeping, and reporting requirements have been added to the standards as well as a requirement for a one-time performance test. These requirements were fully described in the preamble to the proposed revisions (49 FR 50146, December 26, 1984).

In response to comments received on the proposed requirements, an alternative monitoring/recordkeeping/reporting provision has been added to the standards. This alternative allows each owner or operator of a mercury-cell chlor-alkali plant the option of developing and submitting for approval a plant-specific monitoring plan. To be approved, an alternative monitoring plan must adhere to the guidelines that are provided in the regulation.

The proposed standards required each owner or operator of a mercury-cell chlor-alkali plant that uses housekeeping practices to comply with the standard for cell room ventilation systems to maintain daily records of all leaks or spills of mercury in the cell room. These requirements have not changed.

As explained in the preamble to the proposed revisions and in the background document for the promulgated standards, the review of the standards did not indicate a need to revise the emission limits for the three source categories that are covered by the standards or to regulate additional sources of mercury emissions under these standards at this time.

II. Summary of Impacts of the Revisions

Extending the time limit for the submission of test data is intended to improve the quality of test results that are submitted and should have no environmental, economic, cost or energy impacts.

The addition of monitoring, recordkeeping, and reporting requirements for mercury-cell chlor-alkali plants will benefit the environment by encouraging plant operators to adopt the best practices for operating and maintaining process equipment and control devices. The additional reduction in mercury emissions has not been quantified. The average yearly cost to each plant during the first 3 years that the revisions are in

effect would be approximately \$9,000. Most of this cost is attributable to the one-time performance test.

III. Public Participation

Prior to proposal of the revisions, interested parties were advised by public notice in the **Federal Register** (48 FR 50606, November 2, 1983) of a meeting of the National Air Pollution Control Techniques Advisory Committee to discuss recommended revisions to the mercury standard. This meeting was held on November 29, 1983. The meeting was open to the public, and each attendee was given an opportunity to comment on the standards recommended for proposal.

The proposed revisions were published in the **Federal Register** on December 26, 1984 (49 FR 50146). The preamble to the proposed revisions discussed the availability of the review document, which summarized the emissions information gathered during the review, and of the health effects document, which summarized current information on potential health effects associated with mercury exposures. Public comments were solicited at the time of proposal, and copies of the documents were distributed to interested parties.

To provide interested persons the opportunity for oral presentation of data, views, or arguments concerning the proposed standards, the opportunity for a public hearing was provided. However, a public hearing was not requested. The public comment period was from December 26, 1984, to March 13, 1985. Ten comment letters were received concerning issues relative to the proposed revisions and to the conclusions drawn as a result of the review. The comments have been carefully considered and, where determined to be appropriate by the Administrator, changes have been made in the proposed revisions.

IV. Major Comments Received and Changes to the Proposed Revisions

The Agency received two major comments on the proposed monitoring and recordkeeping requirements for mercury-cell chlor-alkali plants. Chlor-alkali plant representatives commented that the standards should allow submittal (to the Administrator) of plant-specific compliance plans as an alternative to the proposed monitoring requirements. Various reasons supporting such a provision were provided by the commenters (and are summarized in section 2.1 of the review document). In response to these comments, the standards were revised to provide for the option of submittal of

alternative plant-specific monitoring plans. Owners and operators who elect to submit such plans must adhere to the seven guidelines stated in § 61.55(c) of the regulation. The monitoring plan must ensure not only compliance with the emission limits but also proper operation and maintenance of emissions control systems.

Several commenters believed that the requirement to record all incidences of mercury leaks or spills should be changed to require recording only incidences of unpredictable or significant leaks or spills that require immediate corrective actions. While the Agency agrees that the leaks or spills of primary interest are those that are "significant," neither the Agency nor representatives from several chlor-alkali companies could offer an acceptable definition of a "significant" leak or spill. Without such a definition, the commenters' request could not be adopted.

One major comment was received in the area of EPA's evaluation of indirect exposures to mercury emissions. The commenter claimed that the Agency's ambient air guideline of 1.0 microgram of mercury per cubic meter of air was based solely on the health effects of inhaled mercury and ignored exposures to mercury emissions that are deposited on land, water, or other surfaces. This commenter believed a re-evaluation of the ambient guideline level was warranted and that the re-evaluation should take into account total human exposures to mercury, including deposited mercury in its more toxic methylated forms.

As stated in section 2.5 of the review document, the Agency considered mercury exposures from dietary ingestion as well as from inhalation in setting the ambient air guideline level. The guideline level also includes a safety factor of ten. However, the effects of mercury emissions on other environments (such as drinking water) and the accumulation of methyl mercury in food (primarily fish) were not fully addressed in the NESHAP review. The EPA is presently reviewing available information concerning these effects, and studies are currently underway to gather the necessary data. These include studies of biochemical mechanisms (for example, the biochemical cycling of mercury) and health and environmental effects (for example, the bioaccumulation of methylmercury in fish) from the deposition of mercury. A preliminary report of the results of studies addressing the bioaccumulation of mercury in fish (the primary source of ingested mercury) is scheduled for 1989 with an integrated report on mercury

bioaccumulation scheduled for 1992. As the results of these studies become available, the Agency will take action as appropriate. However, at this time, the Agency does not have a sufficient basis for revising the ambient guideline level.

One commenter believed the Agency should re-evaluate its decision not to regulate mercury emissions from power plants. This commenter believed the Agency should revise its calculations of mercury emissions to include coals with higher mercury contents than those assumed in the calculations. The commenter referred to reports of mercury concentrations in some American coals as high as 1.6 parts per million (ppm), a level four times higher than the concentration that was used in the Agency's analysis. He stated that the Agency cannot conclude that the ambient guideline will not be exceeded until an analysis of the ambient concentrations expected from plants burning high-mercury coals is completed.

The commenter also objected to EPA's approach to regulating toxic emissions from coal-fired boilers. He stated that by analyzing toxic components of boiler emissions one-by-one, there is a strong bias against control since only a fraction of the total health risk is compared with the total control cost. The commenter believed that EPA should abandon this approach and should require the use of particulate control techniques to capture all toxic emissions, including mercury.

To examine the potential for mercury emissions from coal-fired power plants to exceed the ambient air guideline, the Agency reviewed the data on the mercury content of coals available in the United States (Docket item IV-B-1). The highest mercury level reported for the 48 contiguous states is 8 parts per million (ppm) for subbituminous coal and 3.3 ppm for bituminous coal with an average of 0.1 ppm for subbituminous coal and 0.21 ppm for bituminous coal. The worst case estimates for a large 4000 megawatt (MW) coal-fired power plant firing 8 ppm subbituminous coal is 870 pounds of mercury per day. According to dispersion estimates, a 4000 MW plant emitting 790 pounds of mercury per day would cause a maximum ground level concentration of $1.0 \mu\text{g}/\text{m}^3$. This indicates that in the extreme case a large coal-fired power plant could emit mercury at levels high enough to exceed the ambient guideline. However, typically, mercury emissions from coal-fired power plants are expected to be well below the ambient guideline level.

The Agency is currently studying the combined effect of identified trace

element (including mercury) emissions from fossil-fuel combustion. For mercury, estimates are being made of nationwide emissions and of maximum concentrations associated with four sectors of coal burning: utility, industrial, commercial, and residential combustors. The results of this study will be used to determine the need and appropriate mechanism for regulating mercury emissions from fossil-fuel combustion.

Another major comment received pertained to mercury emissions from synthetic fuel processes. The commenter stated that there are data indicating that mercury emissions from oil shale retort operations can equal or exceed emissions from the currently regulated source categories. He believed these data demonstrate the need to set a national emission standard for mercury emissions from oil shale retorting and the need to examine the potential for mercury emissions from other synthetic fuel processes that are under active consideration.

At the present time there is only one retort plant in operation in the United States that is capable of processing more than 100 tons per day of raw shale to produce crude oil. Estimates of mercury emissions from this operation indicate that ambient mercury levels would be less than 0.04 $\mu\text{g}/\text{m}^3$, a level well below the ambient guideline level of 1.0 $\mu\text{g}/\text{m}^3$ (Docket item IV-A-2).

Construction of new retort operations or startup of existing plants that have been shut down is not anticipated in the near future. Furthermore, projections of mercury emissions from hypothetical commercial-scale operations indicate that emissions from a large size facility would still be below the ambient guideline level (Docket item IV-A-2).

In view of the low level of emissions from the oil shale retort that is currently in operation and the lack of anticipated growth in this industry in the near future, oil shale retorting operations are not being added as a source category to be regulated by the current mercury NESHAP. If oil shale retort operations become economically feasible, the Agency will review its decision not to regulate mercury emissions from these operations under these standards.

V. Administrative

The docket is an organized and complete file of all the information considered by EPA in the development of this rulemaking. The docket is a dynamic file, since material is added throughout the rulemaking development. The docketing system is intended to allow members of the public and industries involved to readily identify

and locate documents so that they can effectively participate in the rulemaking process. Along with the statement of basis and purpose of the proposed and promulgated standards and EPA responses to significant comments, the contents of the docket, except for interagency review materials, will serve as the record in case of judicial review [section 307(d)(7)(A)].

As prescribed by section 112, the promulgation of these standards was preceded by the Administrator's earlier determination that mercury is a hazardous air pollutant. This determination was based on the finding that previously unregulated mercury emissions might cause or contribute to an increase in serious irreversible, or incapacitating reversible, illness. The intent of the standards is to protect the public health with an ample margin of safety. In accordance with section 117 of the Act, publication of these promulgated standards was preceded by consultation with appropriate advisory committees, independent experts, and Federal departments and agencies.

This regulation will be reviewed again 5 years from the date of this promulgation. This review will include an assessment of such factors as the need for integration with other programs, the existence of alternative control methods, enforceability, improvements in emission control technology, and reporting requirements.

Information collection requirements associated with this regulation (those included in 40 CFR Part 61, Subpart A and Subpart E) have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number 2060-0097.

Under Executive Order 12291, EPA is required to judge whether a regulation is a "major rule" and therefore subject to the requirements of a regulatory impact analysis (RIA). The Agency has determined that this regulation would result in none of the adverse economic effects set forth in Section 1 of the Order as grounds for finding a regulation to be a "major rule." This regulation will not have an annual effect on the economy of \$100 million or more, result in a major increase in costs or prices, or have significant adverse effects on competition, employment, investment productivity, or innovation. The Agency has, therefore, concluded that this regulation is not a "major rule" under Executive Order 12291.

The Regulatory Flexibility Act of 1980 requires the identification of potentially adverse impacts of Federal regulations

upon a substantial number of small business entities. The Act specifically requires the completion of a Regulatory Flexibility Analysis in those instances where small business impacts are possible. None of the companies affected by these revisions meets the Small Business Administration definition of a small business, and thus, no regulatory flexibility analysis was required.

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 40 CFR Part 61

Air pollution control, Asbestos, Beryllium, Hazardous substances, Mercury, Radionuclides, Reporting and recordkeeping requirements, Vinyl chloride.

Dated: March 11, 1987.

Lee M. Thomas,
Administrator.

PART 61—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS

For reasons set out in the preamble, 40 CFR Part 61, Subpart E, is amended as set forth below.

1. The authority citation for Part 61 continues to read as follows:

Authority: 42 U.S.C. 7412, 7414, and 7601(a).

2. Section 61.53 is amended by revising paragraphs (a)(4), (b)(4), (c)(4), and (d)(5) to read as follows:

§ 61.53 Stack sampling.

(a) * * *

(4) All samples shall be analyzed and mercury emissions shall be determined within 30 days after the stack test. Each determination shall be reported to the Administrator by a registered letter dispatched within 15 calendar days following the date such determination is completed.

* * * * *

(b) * * *

(4) All samples shall be analyzed and mercury emissions shall be determined within 30 days after the stack test. Each determination shall be reported to the Administrator by a registered letter dispatched within 15 calendar days following the date such determination is completed.

* * * * *

(c) * * *

(4) An owner or operator may carry out approved design, maintenance, and housekeeping practices. A list of approved practices is provided in

Appendix A of "Review of National Emission Standards for Mercury," EPA-450/3-84-014a, December 1984. Copies are available from EPA's Central Docket Section, Docket item number A-84-41, III-B-1.

(d) ***

(5) All samples shall be analyzed and mercury emissions shall be determined within 30 days after the stack test. Each determination shall be reported to the Administrator by a registered letter dispatched within 15 calendar days following the date such determination is completed.

* * * * *

3. Section 61.54 is amended by revising paragraph (f) to read as follows:

§ 61.54 Sludge sampling.

* * * * *

(f) All sludge samples shall be analyzed for mercury content within 30 days after the sludge sample is collected. Each determination shall be reported to the Administrator by a registered letter dispatched within 15 calendar days following the date such determination is completed.

* * * * *

4. Section 61.55 is amended by revising the title and paragraph (a) and by adding paragraphs (b), (c), and (d) as follows:

§ 61.55 Monitoring of emissions and operations.

(a) Wastewater treatment plant sludge incineration and drying plants. All the sources for which mercury emissions exceed 1,600 g per 24-hour period, demonstrated either by stack sampling according to § 61.53 or sludge sampling according to § 61.54, shall monitor mercury emissions at intervals of at least once per year by use of Method 105 of Appendix B or the procedures specified in § 61.53 (d) (2) and (4). The results of monitoring shall be reported and retained according to § 61.53(d) (5) and (6) or § 61.54 (f) and (g).

(b) Mercury cell chlor-alkali plants—hydrogen and end-box ventilation gas streams.

(1) The owner or operator of each mercury cell chlor-alkali plant shall, within 1 year of the date of publication of these amendments or within 1 year of startup for a plant with initial startup after the date of publication, perform a mercury emission test that demonstrates compliance with the emission limits in § 61.52, on the hydrogen stream by Reference Method 102 and on the end-box stream by Reference Method 101 for the purpose of establishing limits for parameters to be monitored.

(2) During tests specified in paragraph (b)(1) of this section, the following control device parameters shall be monitored, except as provided in paragraph (c) of this section, and recorded manually or automatically at least once every 15 minutes:

(i) The exit gas temperature from uncontrolled streams;

(ii) The outlet temperature of the gas stream for the final (i.e., the farthest downstream) cooling system when no control devices other than coolers and demisters are used;

(iii) The outlet temperature of the gas stream from the final cooling system when the cooling system is followed by a molecular sieve or carbon adsorber;

(iv) Outlet concentration of available chlorine, pH, liquid flow rate, and inlet gas temperature of chlorinated brine scrubbers and hypochlorite scrubbers;

(v) The liquid flow rate and exit gas temperature for water scrubbers;

(vi) The inlet gas temperature of carbon adsorption systems; and

(vii) The temperature during the heating phase of the regeneration cycle for carbon adsorbers or molecular sieves.

(3) The recorded parameters in paragraphs (b)(2)(i) through (b)(2)(vi) of this section shall be averaged over the test period (a minimum of 6 hours) to provide an average number. The highest temperature reading that is measured in paragraph (b)(2)(vii) of this section is to be identified as the reference temperature for use in paragraph (b)(6)(ii) of this section.

(4)(i) Immediately following completion of the emission tests specified in paragraph (b)(1) of this section, the owner or operator of a mercury cell chlor-alkali plant shall monitor and record manually or automatically at least once per hour the same parameters specified in paragraphs (b)(2)(i) through (b)(2)(vi) of this section.

(ii) Immediately following completion of the emission tests specified in paragraph (b)(1) of this section, the owner or operator shall monitor and record manually or automatically, during each heating phase of the regeneration cycle, the temperature specified in paragraph (b)(2)(vii) of this section.

(5) Monitoring devices used in accordance with paragraphs (b)(2) and (b)(4) of this section shall be certified by their manufacturer to be accurate to within 10 percent, and shall be operated, maintained, and calibrated according to the manufacturer's instructions. Records of the certifications and calibrations shall be retained at the chlor-alkali plant and made available for inspection by

the Administrator as follows:

Certification, for as long as the device is used for this purpose; calibration for a minimum of 2 years.

(6)(i) When the hourly value of a parameter monitored in accordance with paragraph (b)(4)(i) of this section exceeds, or in the case of liquid flow rate and available chlorine falls below the value of that same parameter determined in paragraph (b)(2) of this section for 24 consecutive hours, the Administrator is to be notified within the next 10 days.

(ii) When the maximum hourly value of the temperature measured in accordance with paragraph (b)(4)(ii) of this section is below the reference temperature recorded according to paragraph (b)(3) of this section for three consecutive regeneration cycles, the Administrator is to be notified within the next 10 days.

(7) Semiannual reports shall be submitted to the Administrator indicating the time and date on which the hourly value of each parameter monitored according to paragraphs (b)(4)(i) and (b)(4)(ii) of this section fell outside the value of that same parameter determined under paragraph (b)(3) of this section; and corrective action taken, and the time and date of the corrective action. Parameter excursions will be considered unacceptable operation and maintenance of the emission control system. In addition, while compliance with the emission limits is determined primarily by conducting a performance test according to the procedures in § 61.53(b), reports of parameter excursions may be used as evidence in judging the duration of a violation that is determined by a performance test.

(8) Semiannual reports required in paragraph (b)(7) of this section shall be submitted to the Administrator on September 15 and March 15 of each year. The first semiannual report is to be submitted following the first full 6 month reporting period. The semiannual report due on September 15 (March 15) shall include all excursions monitored through August 31 (February 28) of the same calendar year.

(c) As an alternative to the monitoring, recordkeeping, and reporting requirements in paragraphs (b)(2) through (8) of this section, an owner or operator may develop and submit for the Administrator's review and approval a plant-specific monitoring plan. To be approved, such a plan must ensure not only compliance with the emission limits of § 61.52(a) but also proper operation and maintenance of emissions control systems. Any site-specific monitoring

plan submitted must, at a minimum, include the following:

(1) Identification of the critical parameter or parameters for the hydrogen stream and for the end-box ventilation stream that are to be monitored and an explanation of why the critical parameter(s) selected is the best indicator of proper control system performance and of mercury emission rates.

(2) Identification of the maximum or minimum value of each parameter (e.g., degrees temperature, concentration of mercury) that is not to be exceeded. The level(s) is to be directly correlated to the results of a performance test, conducted no more than 180 days prior to submittal of the plan, when the facility was in compliance with the emission limits of § 61.52(a).

(3) Designation of the frequency for recording the parameter measurements, with justification if the frequency is less than hourly. A longer recording frequency must be justified on the basis of the amount of time that could elapse during periods of process or control system upsets before the emission limits would be exceeded, and consideration is

to be given to the time that would be necessary to repair the failure.

(4) Designation of the immediate actions to be taken in the event of an excursion beyond the value of the parameter established in 2.

(5) Provisions for reporting, semiannually, parameter excursions and the corrective actions taken, and provisions for reporting within 10 days any significant excursion.

(6) Identification of the accuracy of the monitoring device(s) or of the readings obtained.

(7) Recordkeeping requirements for certifications and calibrations.

(d) Mercury cell chlor-alkali plants—cell room ventilation system.

(1) Stationary sources determining cell room emissions in accordance with § 61.53(c)(4) shall maintain daily records of all leaks or spills of mercury. The records shall indicate the amount, location, time, and date the leaks or spills occurred, identify the cause of the leak or spill, state the immediate steps taken to minimize mercury emissions and steps taken to prevent future occurrences, and provide the time and

date on which corrective steps were taken.

(2) The results of monitoring shall be recorded, retained at the source, and made available for inspection by the Administrator for a minimum of 2 years.

(Approved by the Office of Management and Budget under control number 2060-0097)

5. Section 61.56 is added to Subpart E to read as follows:

§ 61.56 Delegation of authority.

(a) In delegating implementation and enforcement authority to a State under section 112(d) of the Act, the authorities contained in paragraph (b) of this section shall be retained by the Administrator and not transferred to a State.

(b) Authorities which will not be delegated to States: Sections 61.53(c)(4) and 61.55(d). The authorities not delegated to States listed are in addition to the authorities in the General Provisions, Subpart A of 40 CFR Part 61, that will not be delegated to States (§§ 61.04(b), 61.12(d)(1), and 61.13(h)(1)(ii)).

[FR Doc. 87-5803 Filed 3-18-87; 8:45 am]

BILLING CODE 6560-50-M

U.S. AIRPORT RADAR SERVICE
Establishment of Airport Radar Service Areas; Proposed Rule

Thursday
March 19, 1987

Part V

**Department of
Transportation**

Federal Aviation Administration

14 CFR Part 71
Establishment of Airport Radar Service
Areas; Proposed Rule

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Airspace Docket No. 86-AWA-42]

Proposed Establishment of Airport Radar Service Areas**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish Airport Radar Service Areas (ARSA) at four locations—Akron-Canton Regional Airport, OH; Grand Rapids Kent County International Airport, MI; Rochester-Monroe County Airport, NY, and Toledo Express Airport, OH. Each location is a public airport at which a nonregulatory Terminal Radar Service Area (TRSA) is currently in effect. Establishment of each ARSA would require that pilots maintain two-way radio communication with air traffic control (ATC) while in the ARSA. Implementation of ARSA procedures at each of the affected locations would promote the efficient control of air traffic and reduce the risk of midair collision in terminal areas.

DATES: Comments must be received on or before July 22, 1987. Informal airspace meeting dates are as follows: Akron-Canton Regional Airport, OH—May 13, 1987; Grand Rapids Kent County International Airport, MI—May 12, 1987; Rochester-Monroe County Airport, NY—June 10, 1987, and Toledo Express Airport, OH—May 14, 1987.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket [AGC-204], Airspace Docket No. 86-AWA-42, 800 Independence Avenue, SW., Washington, DC 20591.

Informal airspace meeting places are as follows:

Akron-Canton Regional Airport, OH, ARSA

Time: 7:00 p.m.

Location: Stark Technical College Auditorium, 6200 Franklin Avenue, NW., Canton, OH

Grand Rapids Kent County International Airport, MI, ARSA

Time: 6:00 p.m.

Location: Kent County International Airport Terminal Building, Basement Conference Room, 5500 44th Street, SE., Grand Rapids, MI

Rochester-Monroe County Airport, NY, ARSA

Time: 7:30 p.m.

Location: Sperry High School, Lehigh Station Road, Henrietta, NY

Toledo-Express Airport, OH, ARSA

Time: 7:00 p.m.

Location: University of Toledo, Driscoll Center Auditorium of Continuing Education, West Bancroft Street and University Hills Boulevard, Toledo, OH

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, DC.

Informal dockets may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT:

Robert G. Burns, Airspace and Air Traffic Rules Branch (ATO-230), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9253.

SUPPLEMENTARY INFORMATION:**Comments Invited**

This notice involves four locations. Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 86-AWA-42." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-230, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-3484.

Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2 which describes the application procedure.

Meeting Procedures

In addition to seeking written comments on this proposal, the FAA will hold informal airspace meetings for all proposed ARSA locations in order to receive additional input with respect to the proposal. The schedule of times and places of the hearings is listed above. No individual meetings will be held at the same time on separate locations in the same region, so that commenters will be able to attend all meetings in which they may have an interest. Persons who plan to attend any of the meetings should be aware of the following procedures to be followed:

(a) The meetings will be informal in nature and will be conducted by the designated representative of the Administrator. Each participant will be given an opportunity to make a presentation.

(b) The dates, times, and places for each meeting are listed above. There will be no admission fee or other charge to attend and participate. The meetings will be open to all persons on a space-available basis. The FAA representative may accelerate the agenda to enable early adjournment if the progress of any meeting is more expeditious than planned.

(c) The meetings will not be recorded. A summary of the comments made at each meeting will be filed in the docket.

(d) Position papers or other handout material relating to the substance of the meetings may be accepted at the discretion of the FAA representative. Participants submitting handout materials should present an original and two copies to the presiding officer for approval before distribution. If approved by the presiding officer, there should be an adequate number of copies provided for further distribution to all participants.

(e) Statements made by FAA participants at the meetings should not

be taken as expressing a final FAA position.

Agenda

Presentation of Meeting Procedures
FAA Presentation of Proposal
Public Presentations and Discussion

Background

On April 22, 1982, the National Airspace Review (NAR) plan was published in the *Federal Register* (47 FR 17448). The plan encompassed a review of airspace use and procedural aspects of the ATC system. Among the main objectives of the NAR were the improvement of the ATC system by increasing efficiency and reducing complexity. In its review of terminal airspace, NAR Task Group 1-2 concluded that TRSA's should be replaced. Four types of airspace configurations were considered as replacement candidates, of which Model B, since redesignated ARSA, was the consensus recommendation.

In response, the FAA published NAR Recommendation 1-2.2.1, "Replace Terminal Radar Service Areas with Model B Airspace and Service" in Notice 83-9 (July 28, 1983; 48 FR 34286) proposing the establishment of ARSA's at the Robert Mueller Municipal Airport, Austin, TX, and the Port of Columbus International Airport, Columbus, OH. ARSA's were designated at these airports on a temporary basis by SFAR No. 45 (October 28, 1983; 48 FR 50038) in order to provide an operational confirmation of the ARSA concept for potential application on a national basis.

Following a confirmation period of more than a year, the FAA adopted the NAR recommendation and, on February 27, 1985, issued a final rule (50 FR 9252; March 6, 1985) defining an ARSA and establishing air traffic rules for operation within such an area. Concurrently, by separate rulemaking action, ARSA's were permanently established at the Austin, TX, and Columbus, OH, airports and also at the Baltimore/Washington International Airport, Baltimore, MD. (50 FR 9250; March 6, 1985). The FAA has stated that future notices would propose ARSA's for other airports at which TRSA procedures were in effect.

Additionally, the NAR Task Group recommended that the FAA develop quantitative criteria for proposing to establish ARSA's at locations other than those which are included in the TRSA replacement program. The task group recommended this criteria consider—among other things—traffic mix, flow and density, airport configuration, geographical features, collision risk

assessment, and ATC capabilities to provide service to users. This criteria has been developed and is being published via the FAA directives system.

The FAA has established ARSA's at 69 locations under a paced implementation plan to replace TRSA's with ARSA's. This is one of a series of notices to implement ARSA's at locations with TRSA's.

Related Rulemaking

This notice proposes ARSA designation at four of the locations identified as candidates for an ARSA in the preamble to Amendment No. 71-10 (50 FR 9252). Other candidate locations will be proposed in future notices published in the *Federal Register*.

The Current Situation at the Proposed ARSA Locations

A TRSA is currently in effect at each of the locations at which ARSA's are proposed in this notice. A TRSA consists of the airspace surrounding a designated airport where ATC provides radar vectoring, sequencing, and separation for all aircraft operating under instrument flight rules (IFR) and for participating aircraft operating under visual flight rules (VFR). TRSA airspace and operating rules are not established by regulation, and participation by pilots operating under VFR is voluntary, although pilots are urged to participate. This level of service is known as Stage III and is provided at all locations identified as TRSA's. The NAR task group recommended the replacement of most TRSA's with ARSA's.

A number of problems with the TRSA program were identified by the task group. The task group stated that because there are different levels of service offered within the TRSA, users are not always sure of what restrictions or privileges exist, or how to cope with them. According to the task group, there is a feeling shared among users that TRSA's are often poorly defined, are generally dissimilar in dimensions, and encompass more area than is necessary or desirable. There are other users who believe that the voluntary nature of the TRSA does not adequately address the problems associated with nonparticipating aircraft operating in relative proximity to the airport and associated approach and departure courses. There is strong advocacy among user organizations that terminal radar facilities should provide all pilots the same service, in the same way, and, to the extent feasible, within standard size airspace designations.

Certain provisions of FAR § 91.87 add to the problem identified by the task

group. For example, aircraft operating under VFR to or from a satellite airport and within the airport traffic area (ATA) of the primary airport are excluded from the two-way radio communications requirement of § 91.87. This condition is acceptable until the volume and density of traffic at the primary airport dictates further action.

The Proposal

The FAA is considering an amendment to § 71.501 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to establish ARSA's at the following four locations: Akron-Canton Regional Airport, OH; Grand Rapids Kent County International Airport, MI; Rochester-Monroe County Airport, NY, and Toledo Express Airport, OH. Each of the above locations is a public airport at which a nonregulatory TRSA is currently in effect. The proposed locations are depicted on charts in Appendix 1 to this notice.

The FAA has published a final rule (50 FR 9252; March 6, 1985) which defines ARSA and prescribes operating rules for aircraft, ultralight vehicles, and parachute jump operations in airspace designated as an ARSA.

The final rule provides in part that any aircraft arriving at any airport in an ARSA or flying through an ARSA, prior to entering the ARSA must: (1) Establish two-way radio communications with the ATC facility having jurisdiction over the area, and (2) while in the ARSA, maintain two-way radio communications with that ATC facility. For aircraft departing from the primary airport within the ARSA, two-way radio communications must be maintained with the ATC facility having jurisdiction over the area. For aircraft departing a satellite airport within the ARSA, two-way radio communications must be established as soon as practicable after takeoff with the ATC facility having jurisdiction over the area, and thereafter maintained while operating within the ARSA.

All aircraft operating within an ARSA are required to comply with all ATC clearances and instructions and any FAA arrival or departure traffic pattern for the airport of intended operation. However, the rule permits ATC to authorize appropriate deviations to any of the operating requirements of the rule when safety considerations justify the deviation or more efficient utilization of the airspace can be attained. Ultralight vehicle operations and parachute jumps in an ARSA may only be conducted under the terms of an ATC authorization.

The FAA adopted the NAR task group recommendation that each ARSA be of the same airspace configuration insofar as practicable. The standard ARSA consists of airspace within 5 nautical miles of the primary airport extending from the surface to an altitude of 4,000 feet above that airport's elevation, and that airspace between 5 and 10 nautical miles from the primary airport from 1,200 feet above the surface to an altitude of 4,000 feet above that airport's elevation. Proposed deviation from the standard has been necessary at some airports due to adjacent regulatory airspace, international boundaries, topography, or unusual operational requirements.

Definitions, operating requirements, and specific airspace designations applicable to ARSA may be found in 14 CFR Part 71, § 71.14 and § 71.501, and Part 91, § 91.1 and § 91.88.

For the reasons discussed under "Regulatory Evaluation," the FAA has determined that this proposed regulation (1) is not a "major rule" under Executive Order 12291; and (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979).

Regulatory Evaluation

The FAA has conducted a Regulatory Evaluation of the proposed establishment of additional ARSA sites. The major findings of that evaluation are summarized below, and full evaluation is available in the regulatory docket.

a. Costs

Costs which potentially could result from the ARSA program fall into the following categories:

- (1) Air traffic controller staffing, controller training, and facility equipment costs incurred by the FAA.
- (2) Costs associated with the revision of charts, notification of the public and pilot education.
- (3) Additional operating costs for circumnavigating or flying over the ARSA.
- (4) Potential delay costs resulting from operations within an ARSA rather than a TRSA.

(5) The need for some operators to purchase radio transceivers.

(6) Miscellaneous costs.

It has been the FAA's experience, however, that these potential costs do not materialize to any appreciable degree, and when they do occur, they are transitional, relatively low in magnitude, or attributable to specific implementation problems that have been experienced at a very small

minority of ARSA sites. The reasons for these conclusions are presented below.

FAA expects that the ARSA program can be implemented without requiring additional controller personnel above current authorized staffing levels because participation at most TRSA locations is already quite high, and the reduced separation standards permitted in ARSA's will allow controllers to absorb the slight increase in participating traffic by handling all traffic much more efficiently. Further, because controller training will be conducted during normal working hours, and existing TRSA facilities already operate the necessary radar equipment, FAA does not expect to incur any appreciable implementation costs. Essentially, the FAA is modifying its terminal radar procedures in the ARSA program in a manner that will make more efficient use of existing resources.

No additional costs are expected to be incurred because of the need to revise sectional charts to remove TRSA airspace depictions and incorporate the new ARSA airspace boundaries. Changes of this nature are routinely made during charting cycles, and the planned effective dates for newly established ARSA's are scheduled to coincide with the regular 6-month chart publication intervals.

Much of the need to notify the public and educate pilots about ARSA operations will be met as a part of this rulemaking proceeding. The informal public meeting being held at each location where an ARSA is being proposed provides pilots with the best opportunity to learn both how an ARSA works and how it will affect their local operations. Because the expenses associated with these public meetings will be incurred regardless of whether or not an ARSA is ultimately established at a proposed site, they are more appropriately considered sunken costs attributable to the rulemaking process rather than costs of the ARSA program. Once the decision has been made to establish an ARSA through a final rule issued in this proceeding, however, any public information costs which follow are strictly attributable to the ARSA program. The FAA expects to distribute a Letter to Airmen to all pilots residing within 50 miles of ARSA sites explaining the operation and configuration of the ARSA finally adopted. The FAA will also issue an Advisory Circular on ARSA's. The combined Letter to Airmen and prorated Advisory Circular costs for the four airports at which ARSA's are being proposed by this notice is estimated to be approximately \$1,800. This cost will

be incurred only once upon the initial establishment of the ARSA's.

Information on ARSA's following implementation of the program will also be disseminated at aviation safety seminars conducted throughout the country by various district offices. These seminars are regularly provided by the FAA to discuss a variety of aviation safety issues, and therefore will not involve additional costs strictly as a result of the ARSA program. Additionally, no significant costs are expected to be incurred as a result of the follow-on user meetings that will be held at each site following implementation of the ARSA to allow users to provide feedback to the FAA on local ARSA operations. These meetings are being held at public or other facilities which are being provided free of charge or at nominal cost. Further, because these meetings are being conducted by local FAA facility personnel, no travel, per diem, or overtime costs will be incurred by regional or headquarters personnel.

FAA anticipates that some pilots who currently transit a TRSA without establishing radio communications or participating in radar services may choose to circumnavigate the mandatory participation airspace of an ARSA rather than participate. Some minor delay costs will be incurred by these pilots because of the additional aircraft variable operating cost and lost crew and passenger time resulting from the deviation. Other pilots may elect to overfly the ARSA, or transit below the 1,200 feet above ground level (AGL) floor between the 5- and 10-nautical-mile rings. Although this will not result in any appreciable delay, a small additional fuel burn will result from the climb portion of the altitude adjustment (which will be offset somewhat by the descent).

FAA recognizes that the potential exists for delay to develop at some locations following establishment of an ARSA. The additional traffic that the radar facilities will be handling as a result of the mandatory participation requirement may, in some instances, result in minor delays to aircraft operations. FAA does not expect such delay to be appreciable. FAA expects that the greater flexibility afforded controllers in handling traffic as a result of the reduced separation standards will keep delay problems to a minimum. Those that do occur will be transitional in nature, diminishing as facilities gain operating experience with ARSA's and learn how to tailor procedures and allocate resources to take fullest advantage of the efficiencies that an ARSA will permit. This has been the

experience at the locations where ARSA's have been in effect for the longest period of time, and is the trend at most of the locations that have been more recently designated.

The FAA does not expect that any operators will find it necessary to install radio transceivers as a result of establishing the ARSA's proposed in this notice. Aircraft operating to and from primary airports already are required to have two-way radio communications capability because of existing airport traffic areas and therefore will not incur any additional costs as a result of the proposed ARSA's. Further, the FAA has made an effort to minimize these potential costs throughout the ARSA program by providing airspace exclusions, or cutouts, for satellite airports located within 5 nautical miles of the ARSA center where the ARSA would otherwise have extended down to the surface. Procedural agreements between the local ATC facility and the affected airports have also been used to avoid radio installation costs.

At some proposed ARSA locations, special situations might exist where establishment of an ARSA could impose certain costs on users of that airspace. However, exclusions, cutouts, and special procedures have been used extensively throughout the ARSA program to alleviate adverse impacts on local fixed base and airport operators. Similarly, the FAA has eliminated potential adverse impacts on existing flight training practice areas, as well as soaring, ballooning, parachuting, ultralight and banner towing activities, by developing special procedures to accommodate these activities through local agreements between ATC facilities and the affected organizations. For these reasons, the FAA does not expect that any such adverse impacts will occur at the candidate ARSA sites proposed in this notice.

b. Benefits

Much of the benefit that will result from ARSA's is nonquantifiable, and is attributable to simplification and standardization of ARSA configurations and procedures, which will eliminate much of the confusion pilots currently experience when operating in nonstandard TRSA's. Further, once experience is gained in ARSA operations, the greater flexibility allowed air traffic controllers in handling traffic within an ARSA will enable them to move traffic more efficiently than they currently are able to under TRSA's. These expected savings may or may not offset the delay that some sites may experience after the

initial establishment of an ARSA, but are expected to eventually provide overall time savings to all traffic. IFR as well as VFR, that exceed delay as both pilots and controllers become more familiar with ARSA operating procedures.

Some of the benefits of the ARSA cannot be specifically attributed to individual candidate airports, but rather will result from the overall improvements in terminal area ATC procedures realized as ARSA's are implemented throughout the country. ARSA's have the potential of reducing both near and actual midair collisions at the airports where they are established. Based upon the experience at the Austin and Columbus ARSA confirmation sites, FAA estimates that near midair collisions may be reduced by approximately 35 to 40 percent. Further, FAA estimates that implementation of the ARSA program nationally may prevent approximately one midair collision every 1 to 2 years throughout the United States. The quantifiable benefits of preventing a midair collision can range from less than \$100,000, resulting from the prevention of a minor nonfatal accident between general aviation aircraft, to \$300 million or more, resulting from the prevention of a midair collision involving a large air carrier aircraft and numerous fatalities. Establishment of ARSA's at the sites proposed in this notice will contribute to these improvements in safety.

c. Comparison of Costs and Benefits

A direct comparison of the costs and benefits of this proposal is difficult for a number of reasons. Many of the benefits of the rule are nonquantifiable, and it is difficult to specifically attribute the standardization benefits, as well as the safety benefits, to individual candidate ARSA sites.

FAA expects that any adjustment problems that may be experienced at new ARSA locations will only be temporary, and that once established, the ARSA program will result in an overall improvement in efficiency in terminal area operations at those airports where ARSA's are established. This has been the experience at the vast majority of ARSA sites that have already been implemented. In addition to these operational efficiency improvements, establishment of the proposed ARSA sites will contribute to a reduction in near and actual midair collisions. For these reasons, FAA expects that establishment of the ARSA sites proposed in this notice will produce long term, ongoing benefits that will far exceed their costs, which are essentially transitional in nature.

International Trade Impact Analysis

This proposed regulation will only affect terminal airspace operating procedures at selected airports within the United States. As such, it will have no affect on the sale of foreign aviation products or services in the United States, nor will it affect the sale of United States aviation products or services in foreign countries.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily and disproportionately burdened by government regulations. Small entities are independently owned and operated small businesses and small not-for-profit organizations. The RFA requires agencies to review rules that may have "a significant economic impact on a substantial number of small entities."

The small entities that could be potentially affected by implementation of the ARSA program are the fixed-base operators, flight schools, agricultural operators and other small aviation businesses located at satellite airports within 5 nautical miles of the ARSA center. If the mandatory participation requirement were to extend down to the surface at these airports, where under current regulations participation in the TRSA and radio communication with ATC is voluntary, operations at these airports might be altered, and some business could be lost to airports outside of the ARSA core. FAA has proposed to exclude almost every satellite airport located within 5 nautical miles of the primary airport at candidate ARSA sites to avoid adversely impacting their operations, and to simplify coordinating ATC responsibilities between the primary and satellite airports. In some cases, the same purposes will be achieved through Letters of Agreement between ATC and the affected airports that establish special procedures for operating to and from these airports. In this manner, FAA expects to virtually eliminate any adverse impact on the operations of small satellite airports that potentially could result from the ARSA program. Similarly, FAA expects to eliminate potential adverse impacts on existing flight training practice areas, as well as soaring, ballooning, parachuting, ultralight, and banner towing activities, by developing special procedures that will accommodate these activities through local agreements between ATC facilities and the affected organizations. FAA has utilized such arrangements

extensively in implementing the ARSA's that have been established to date.

Further, because the FAA expects that any delay problems that may initially develop following implementation of an ARSA will be transitory, and because the airports that will be affected by the ARSA program represent only a small proportion of all the public use airports in operation within the United States, small entities of any type that use aircraft in the course of their business will not be adversely impacted.

For these reasons, the FAA certifies that the proposed regulation will not result in a significant economic impact on a substantial number of small entities, and a regulatory flexibility analysis is not required under the terms of the RFA.

List of Subjects 14 CFR Part 71

Aviation safety, Airport radar service areas.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 71.501 [Amended]

2. § 71.501 is amended as follows:

Akron-Canton Regional Airport, OH [New]

That airspace extending upward from the surface to and including 5,200 feet MSL within a 5-mile radius of the Akron-Canton Regional Airport (lat. 40°55'01" N., long. 81°26'30" W.); and that airspace extending upward from 2,500 feet MSL to 5,200 feet MSL within a 10-mile radius of the airport. This airport radar service area is effective during the specific days and hours of operation of the Akron Tower and Approach Control as established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

Grand Rapids Kent County International Airport, MI [New]

That airspace extending upward from the surface to and including 4,800 feet MSL within a 5-mile radius of the Kent County International Airport (lat. 42°52'57" N., long. 85°31'26" W.); and that airspace extending upward from 2,000 feet MSL to 4,800 feet MSL within a 10-mile radius of the airport. This airport radar service area is effective during the specific days and hours of operation of the Grand Rapids Tower and Approach Control as established in advance by a

Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

Rochester-Monroe County Airport, NY [New]

That airspace extending upward from the surface to and including 4,600 feet MSL within a 5-mile radius of the Rochester-Monroe County Airport (lat. 43°07'08" N., long. 77°40'22" W.); and that airspace extending upward from 2,100 feet MSL to 4,600 feet MSL within a 10-mile radius of the airport.

Toledo-Express Airport, OH [New]

That airspace extending upward from the surface to and including 4,700 feet MSL within a 5-mile radius of the Toledo-Express Airport (lat. 41°35'15" N., long. 83°48'19" W.); and that airspace extending upward from 2,000 feet MSL to and including 4,700 feet MSL within a 10-mile radius of the airport. This airport radar service area is effective during the specific days and hours of operation of the Toledo Tower and Approach Control as established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

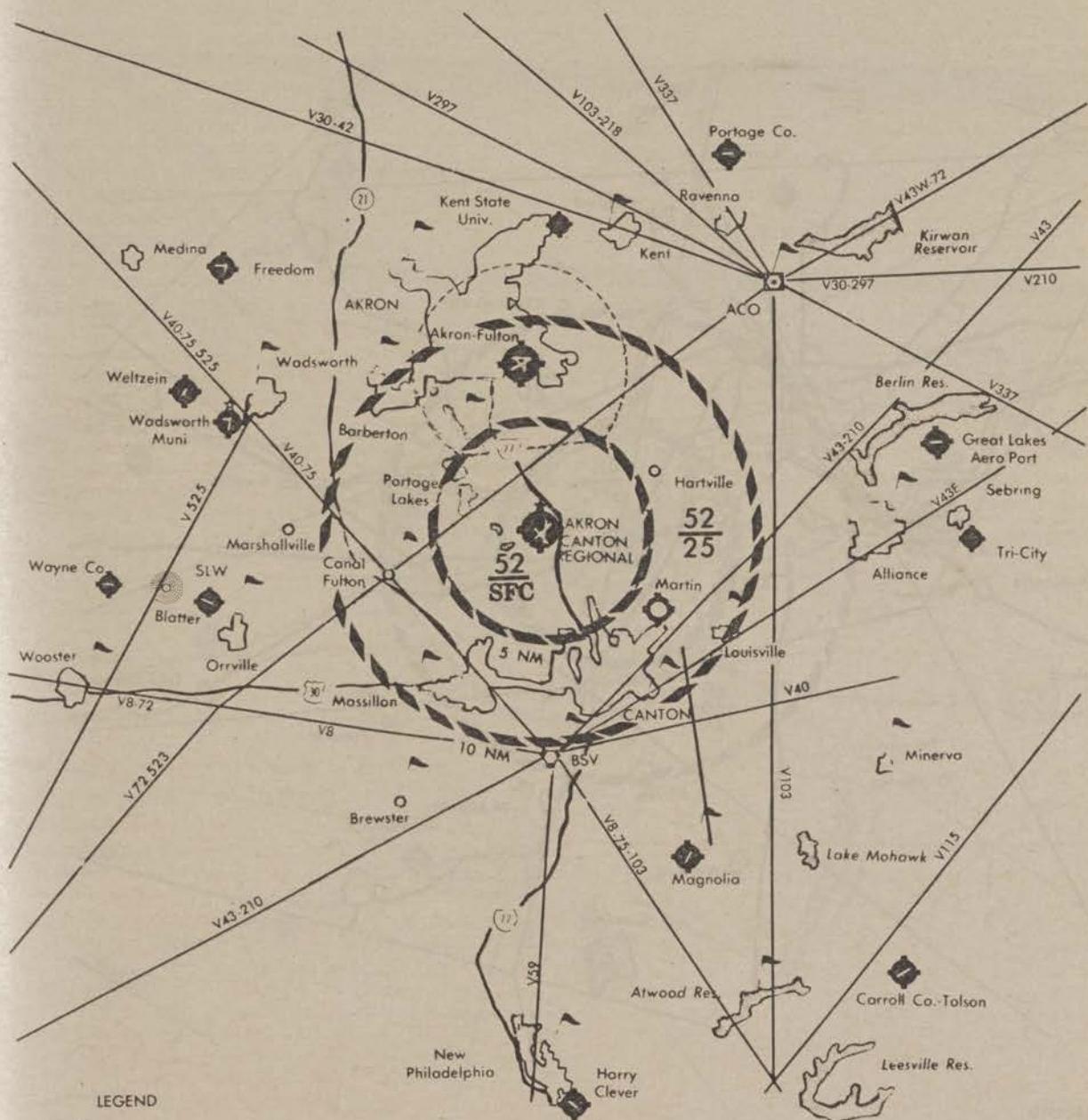
Issued in Washington, DC, on March 12, 1987.

Daniel J. Peterson,

Manager, Airspace-Rules and Aeronautical Information Division.

BILLING CODE 4910-13-M

AIRPORT RADAR SERVICE AREA
(NOT TO BE USED FOR NAVIGATION)
AKRON, OHIO
AKRON-CANTON REGIONAL AIRPORT
FIELD ELEV. 1228' MSL



LEGEND

VFR CHECKPOINT

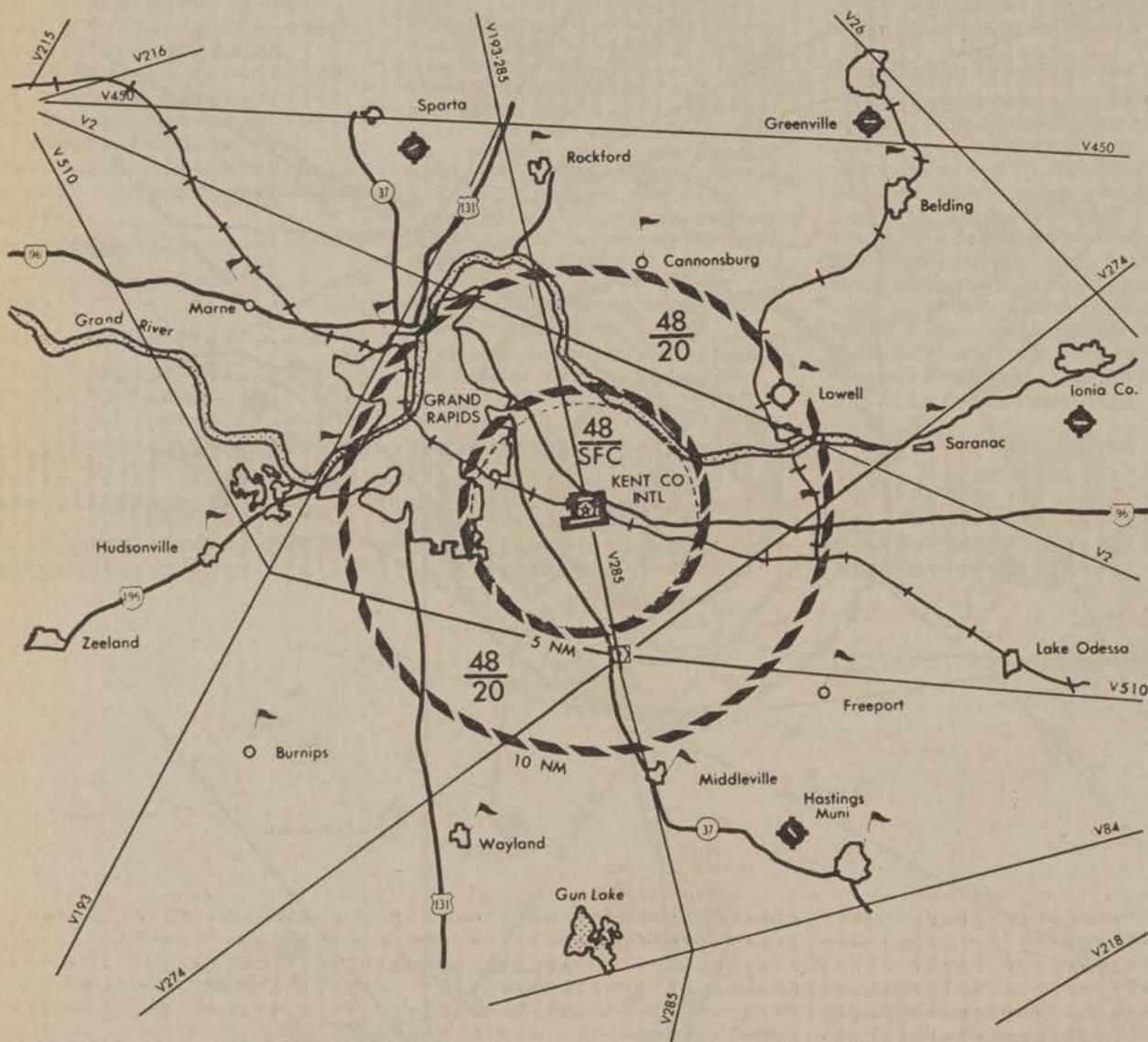
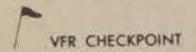
ARSA

ALTITUDES ARE MSL
BEARINGS ARE MAGNETIC

Prepared by the
FEDERAL AVIATION ADMINISTRATION
Cartographic Standards Section
ATO-259

**AIRPORT RADAR SERVICE AREA
(NOT TO BE USED FOR NAVIGATION)**

**GRAND RAPIDS, MICHIGAN
KENT COUNTY INTERNATIONAL AIRPORT
FIELD ELEV. 794' MSL**

**LEGEND**

VFR CHECKPOINT



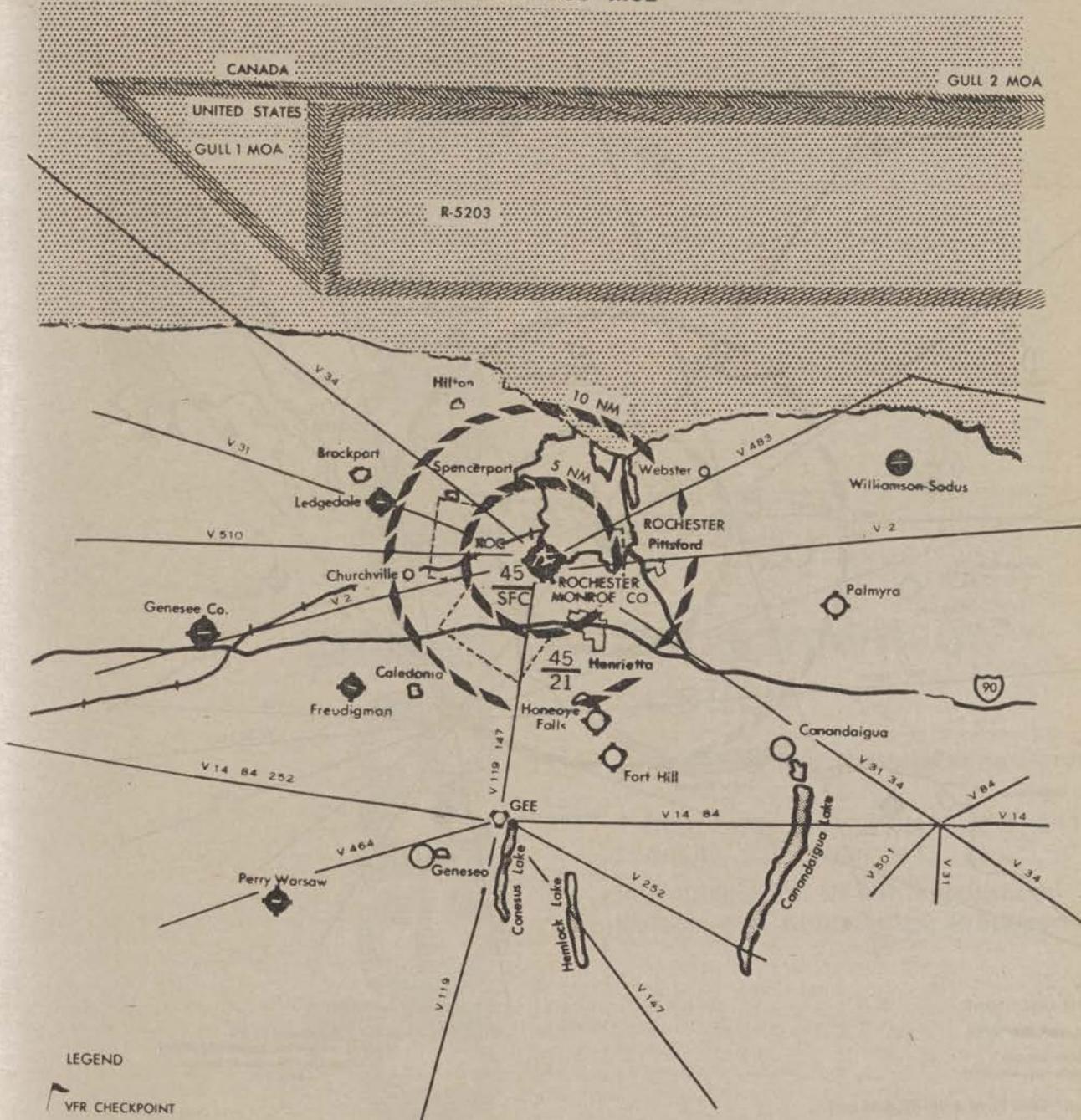
ARSA

ALTITUDES ARE MSL
BEARINGS ARE MAGNETIC

Prepared by the
FEDERAL AVIATION ADMINISTRATION
Cartographic Standards Section
ATO-259

AIRPORT RADAR SERVICE AREA (NOT TO BE USED FOR NAVIGATION)

**ROCHESTER, NEW YORK
ROCHESTER-MONROE COUNTY AIRPORT
FIELD ELEV. 559' MSL**

**LEGEND**

VFR CHECKPOINT

ARSA

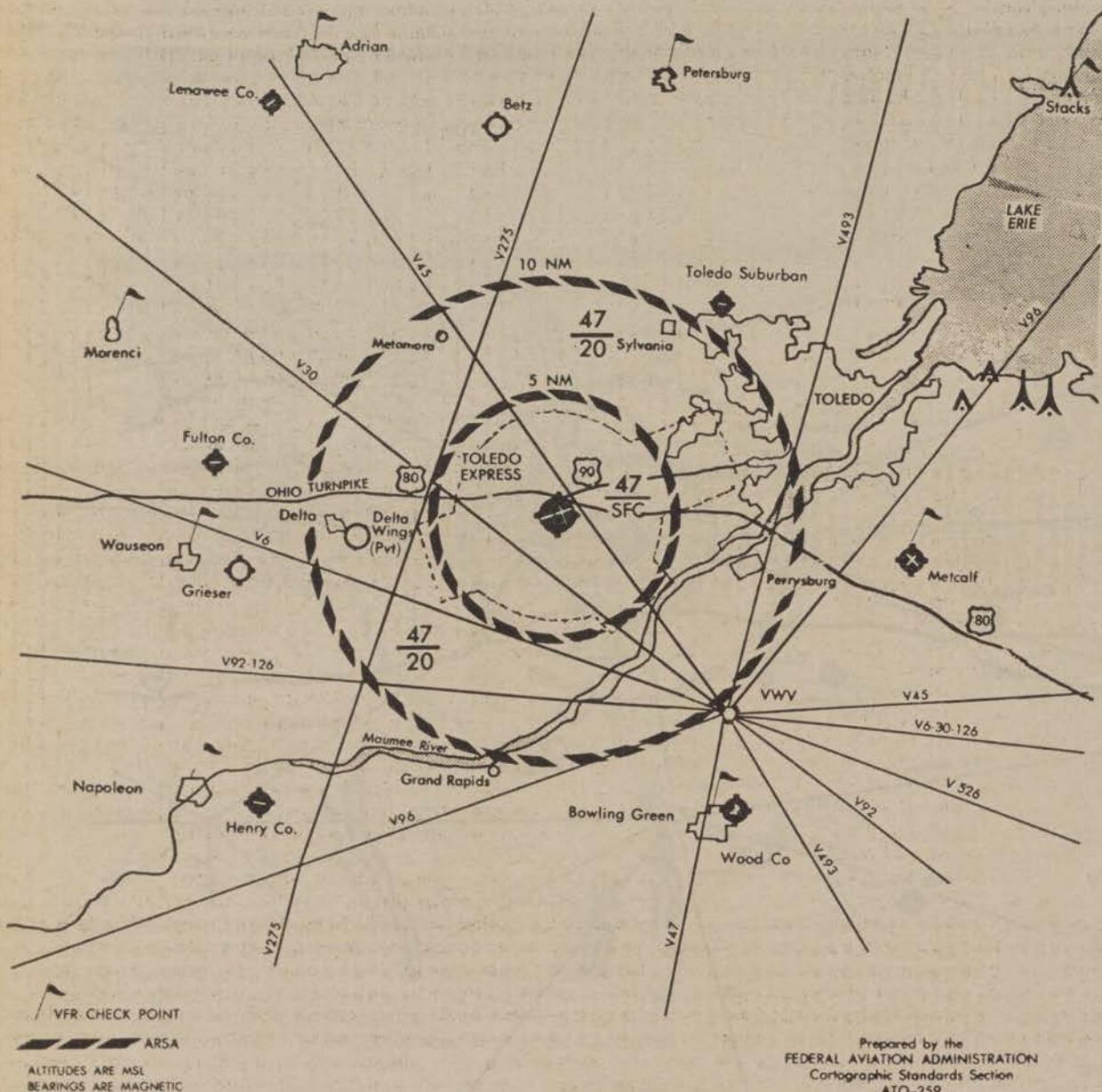
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FEDERAL AVIATION ADMINISTRATION
Cartographic Standards Section
ATO-259

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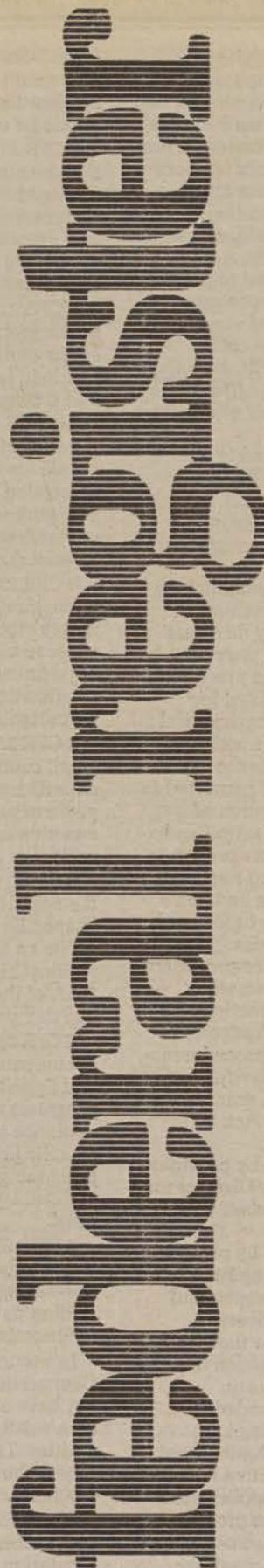
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[FR Doc. 87-5882 Filed 3-18-87; 8:45 am]

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Cartographic Standards Section
ATO-259



Thursday
March 19, 1987

Part VI

**Department of
Justice**

Immigration and Naturalization Service

**8 CFR Parts 100, 103, 109, 210, 211, 212,
234, 242, 245a, 264, 274a, 299**

**Implementation of the Immigration
Reform and Control Act; Proposed Rules**

DEPARTMENT OF JUSTICE**Immigration and Naturalization Service**

8 CFR Parts 100, 103, 211, 212, 234, 242, 264, and 299

Applicant Processing for Special Agricultural Worker and Legalization Programs; Conforming Amendments, etc.

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Proposed rule with requests for comments.

SUMMARY: This proposed rule would set forth conforming amendments to existing regulations to be published elsewhere. These provisions relate to the processing of applicants for lawful temporary resident status under the Special Agricultural Worker and Legalization programs, as authorized by the enactment of the Immigration Reform and Control Act of 1986, also known as the Simpson/Rodino bill.

DATE: Comments must be received on or before April 20, 1987.

ADDRESS: Send original and two copies of comments to Assistant Commissioner for Legalization, Office of Legalization, Room LL-100, INS, 425 I Street, NW., Washington, DC 20536.

FOR FURTHER INFORMATION CONTACT:
William S. Slattery, Assistant Commissioner, Legalization, 425 I Street, NW., Washington, DC 20536, (202) 786-3658.

SUPPLEMENTARY INFORMATION: On November 6, 1986, the Immigration Reform and Control Act of 1986, Pub. L. 99-603 was enacted to provide the opportunity for certain aliens to apply for temporary resident status in the United States, and, under certain conditions, to subsequently apply for permanent resident status.

8 CFR 100.2(c)(3)(vi) adds Legalization as a program falling under the direction of the Associate Commissioner for Examinations.

8 CFR 100.4(f) is added to provide a list of legalization offices which are being opened by the Service to accommodate applicants for the Legalization and Special Agricultural Worker Programs.

8 CFR 103.1(f)(1)(vi) is added to reflect that authority is delegated to the Associate Commissioner for Examinations for the general direction and supervision of the Assistant Commissioner, Legalization.

8 CFR 103.1(f)(2) is amended to reflect that the appellate jurisdiction of the Associate Commissioner, Examinations,

is expanded to include decisions on applications for lawful temporary or permanent resident status under section 245A of the Act, applications for lawful temporary resident status under section 210 of the Act, termination of temporary resident status under section 210 or 245A of the Act, and applications for waiver of grounds of excludability under sections 210 and 245A of the Act.

8 CFR 103.1(n) is amended to provide that an application for temporary residence may be approved at a legalization office after a second interview, and that an application may be denied at a legalization office if the alien is statutorily ineligible or admits fraud.

8 CFR 103.1(q) is amended to add Supervisory Legalization Officers, Legalization Adjudicators and Legalization Assistants to those positions designated as "Immigration Officers."

8 CFR 103.1(t) is added establishing the authority and responsibilities of regional processing facility directors.

8 CFR 103.2(c) is added, providing specific language regarding procedures to follow for applications filed for Legalization and Special Agricultural Worker status. Language is included which expressly recognizes that designated entities will be permitted to assist aliens in the preparation of applications for the Legalization and Special Agricultural Worker programs. Provisions are also made to require designated entities to have an alien's documented authorization to forward the application to the Service.

8 CFR 103.3(a)(2) provides procedures for issuing denials and processing appeals to denials of applications for Legalization and Special Agricultural Worker status. The same procedures apply to cases where the lawful temporary resident status, granted under section 210 or 245A of the Act, is terminated.

8 CFR 103.4 is amended by providing that a Regional Processing Director may certify a decision to the Administrative Appeals Unit.

8 CFR 103.5 is amended by providing that the Regional Processing Facility director may *sua sponte* reopen and reconsider an appealed adverse decision, and establishes a time frame during which any new decision must be served on the appealing party.

8 CFR 103.7(b)(1) is amended to include applications relating to Legalization and Special Agricultural Worker status, and respective fees that will be charged for each application. The cost of the legalization program is to be self funding through application fees. If the revenue collected through the

Form I-687 application fee is not sufficient to cover the costs of the legalization program, an additional fee would be charged to file Form I-698.

8 CFR 211.1(d) establishes documentary requirements for aliens granted lawful temporary resident status under sections 210 and 245A of the Act and prescribes the authorized length of temporary absences abroad while in such status.

8 CFR 211.5 adds language to permit aliens granted lawful temporary resident status under section 210 of the Act to reside in foreign contiguous territory and commute to employment in the United States.

8 CFR 212.5(b) provides for denial of parole for certain aliens seeking admission into the United States for the sole purpose of applying for adjustment of status under the Legalization and Special Agricultural Worker Programs.

8 CFR 212.5(d)(2) provides that an alien granted parole into the United States after November 6, 1986 for any purpose other than applying for adjustment of status under the Legalization program shall not be permitted to apply for Legalization.

8 CFR 234.2(b) is amended to include local, county and state health departments civil surgeons qualified to perform physical and mental examinations of applicants for benefits under the Act.

8 CFR 242.21(b) is added to preclude the appeal to a finding of deportability in specific cases where the alien failed to file an application for temporary resident status under section 210 or 245A of the Act within a defined thirty-one day period.

8 CFR 264.1 is amended to include documents relating to the Legalization and Special Agricultural Worker programs as registration forms and evidence of registration. Additionally, specific procedures are outlined for processing applications for replacement of Form I-688, Temporary Resident Card.

8 CFR 299.1 is amended to include forms to be used in the Legalization and Special Agricultural Worker programs. Edition dates of the forms will be forthcoming.

In accordance with 5 U.S.C. 605(b), the Commissioner certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule is not a major rule within the definition of section 1(b) of EO 12291.

The information collection requirements contained in this regulation will be submitted to OMB for

review under the Paperwork Reduction Act.

List of Subjects

8 CFR Part 100

Administrative practice and procedure, Authority delegations (government agencies).

8 CFR Part 103

Administrative practice and procedure, Authority delegations (government agencies), Fees, Reporting and recordkeeping requirements.

8 CFR Part 211

Reporting and recordkeeping requirements, Visas.

8 CFR Part 212

Administrative practice and procedure, Parole, Reporting and recordkeeping requirements, Visas.

8 CFR Part 234

Public health.

8 CFR Part 242

Administrative practice and procedure, Deportation proceedings.

8 CFR Part 264

Reporting and recordkeeping requirements.

8 CFR Part 299

Forms, Reporting and recordkeeping requirements.

Accordingly, it is proposed to amend Chapter I of Title 8 of the Code of Federal Regulations as follows:

PART 100—STATEMENT OF ORGANIZATION

1. The authority citation for Part 100 is revised to read as follows:

Authority: Sec. 103 of the INA, as amended; 66 Stat. 173; 8 U.S.C. 1103, Pub. L. 99-603.

2. Section 100.2(c)(3) is amended by removing the word "and" from paragraph (iv); removing the period from the end and inserting ", and" in paragraph (v); and adding paragraph (vi) as follows:

§ 100.2 Organization and functions.

(c) * * *

(3) * * *

(vi) Legalization

3. In § 100.4 a new paragraph (f) would be added to read as follows:

§ 100.4 Field service.

(f) District Legalization Offices are local offices of the Immigration and Naturalization Service under the authority of the district director in whose district such offices are located. Legalization Offices are being opened specifically to accommodate applicants for the Legalization and Special Agricultural Worker programs. Legalization Offices may be opened and closed, at the discretion of the Commissioner, as the need arises.

Legalization Offices

Eastern Region

BAL	Baltimore, MD.
BOS	Boston, MA.
	New Haven, CT.
	Springfield, MA.
BUF	Buffalo, NY.
	Syracuse, NY.
NEW	Camden, NJ.
	Jersey City, NJ.
	Paterson, NJ.
NYC	Brooklyn/Queens, NY.
	Manhattan, NY.
	Nassau/Suffolk, NY.
PHI	Lima, PA.
	Pittsburgh, PA.
	Charleston, WV.
SAJ	San Juan, PR.
WA	Arlington, VA.

Northern Region

ANC	Anchorage, AK.
CHI	Four sites to be determined in the greater Chicago area.
	Indianapolis, IN.
	Milwaukee, WI.
CLE	Cincinnati, OH.
	Cleveland, OH.
DEN	Denver, CO.
	Grand Junction, CO.
	Pueblo, CO.
	Salt Lake City, UT.
DET	Detroit, MI.
HEL	Boise, ID.
	Helena, MT.
	Idaho Falls, ID.
KAN	Garden City, KS.
	Kansas City, MO.
	St. Louis, MO.
	Wichita, KS.
OMA	Davenport, IA.
	Des Moines, IA.
	Omaha, NE.
	Scotts Bluff, NE.
POO	Pendleton, OR.
	Portland, OR.

SEA	Pasco, WA.
	Seattle, WA.
	Wenatchee, WA.
	Yakima, WA.
SPM	Twin Cities, MN.

Southern Region

ATL	Atlanta, GA.
DAL	Dallas, TX.
	Lubbock, TX.
	Oklahoma City, OK.
ELP	Albuquerque, NM.
	EL Paso, TX.
HLG	Harlingen, TX.
HOU	Houston, TX.
MIA	Jacksonville, FL.
	Miami, FL.
	Miami, (Opa Locka), FL.
	Miami, (SW), FL.
	Miami, (West Flagler), FL.
	Tampa, FL.
	West Palm, Beach, FL.
NOL	Memphis, TN.
	New Orleans, LA.
SNA	Austin, TX.
	Corpus Christi, TX.
	Laredo, TX.
	San Antonio, TX.

Western Region

HHW	Agana, GU.
	Honolulu, HI.
LOS	Anaheim, CA.
	E. Los Angeles, CA.
	El Monte, CA.
	Hollywood, CA.
	Huntington Park, CA.
	Indio, CA.
	N. Long Beach, CA.
	Norwalk, CA.
	Oxnard, CA.
	Pomona, CA.
	Riverside, CA.
	San Fernando, CA.
	Santa Ana, CA.
	Torrance, Ca.
	Van Nuys, CA.
PHO	Las Vegas, NV.
	Phoenix, AZ.
	Reno, NV.
	Tucson, AZ.
	Willcox, AZ.
	Yuma, AZ.
SND	El Centro, CA.
	Escondido, CA.
	San Diego, CA.
SFR	Bakersfield, CA.
	Eureka, CA.
	Fresno, CA.
	Oakland, CA.
	Redding, CA.
	Sacramento, CA.
	Salinas, CA.
	San Francisco, CA.
	San Jose, CA.
	Stockton, CA.

PART 103—POWERS AND DUTIES OF SERVICE OFFICERS: AVAILABILITY OF SERVICE RECORDS

4. The authority citation for Part 103 is revised to read as follows:

Authority: Sec. 103 of the INA, as amended; 8 U.S.C. 1103, 28 U.S.C. 1746; 31 U.S.C. 9701, EO 12356, Pub. L. 99-603; OMB Circular A-25.

5. Section 103.1 is amended by removing the word "and" for paragraph (f)(1)(iv), inserting "and" at the end of paragraph (f)(1)(v) and adding a new paragraph (f)(1)(vi); adding new paragraph (f)(2)(xxvii)-(xxxii); redesignating existing text in paragraph (n) as (n)(1) and adding a new paragraph (n)(2); inserting "Supervisory Legalization Officer, Legalization Adjudicator, Legalization Assistant" after the word "representative," in paragraph (q); and adding a new paragraph (t) to read as follows:

§ 103.1 Delegations of authority.

(f) * * *

(1) * * *

(vi) Assistant Commissioner, Legalization

(2) * * *

(xxvii) Application for status as temporary or permanent resident under § 245a.2 or § 245a.3 of this title.

(xxviii) Application for status as temporary resident under § 210.2 of this title.

(xxix) Termination of status as temporary resident under § 210.4 of this title.

(xxx) Termination of status as temporary resident under § 245a.2 of this title.

(xxxi) Application for waiver of grounds of excludability under Parts 210 and 245a of this title.

(xxxii) Application for replacement of Form I-688 (Temporary Resident Card).

(n) * * * (1) * * *

(2) Applications filed for Special Agricultural Worker or Legalization status pursuant to sections 210 and 245A, respectively, may be approved by the district director having jurisdiction of the legalization office where a second interview is required by the regional processing facility, if the alien in the second interview can establish eligibility for approval. District directors may deny applications for Special Agricultural Worker or Legalization status at legalization offices under their jurisdiction if the alien fails to meet statutory requirements or the alien admits fraud or misrepresentation in the application process.

(t) *Regional Processing Facility Directors.* Under the direction of their respective regional commissioners, regional processing facility directors have program, administrative and supervisory responsibility for all personnel assigned to their facilities. Regional processing facility directors are delegated the authority and responsibility to approve or deny applications for adjustment of status and for waivers of grounds of excludability under section 210 and section 245A of the Act.

6. In § 103.2, a new paragraph (c) would be added to read as follows:

§ 103.2 Applications, petitions and other documents.

(c) *Filing of applications for adjustment of status under sections 210 and 245A of the Act, as amended.* (1) The filing of an application for temporary resident status under section 245A(a) of the Act must conform to the provisions of § 245a.2 of this chapter. The filing of an application for permanent resident status under section 245A(b)(1) of the Act must conform to the provisions of § 245a.3 of this chapter. The filing of an application for adjustment of status under section 210(a) of the Act must conform to the provisions of § 210.2 of this chapter.

(2) An application for adjustment to temporary or permanent resident status pursuant to section 245A (a) or (b)(1) or section 210(a) of the Act may be accepted on behalf of the Attorney General by designated state, local and community organizations as well as designated voluntary organizations and persons. Each such application shall contain a certification signed by both the alien and the preparing member of the designated organization or entity, that the applicant has approved transmittal of the application to the Service for adjudication.

(3) An application accepted by any of the designated entities shall be stamped with an endorsement as to the date of preparation and authorization for transmittal, and may be brought to the legalization office with the applicant as an application ready for adjudication. However, such application shall not be considered as complete until accepted for adjudication by and until the appropriate fee has been paid to the Immigration and Naturalization Service at the time the alien appears for personal interview by the Service.

7. In § 103.3(a), existing text is redesignated (a)(1) and a new paragraph (a)(2) is added to read as follows:

§ 103.3 Denials, appeals and precedent decisions;

(a) * * *

(1) * * *

(2) *Denials and appeals of special agricultural worker and legalization applications and termination of lawful temporary resident status under sections 210 and 245A.* (i) Whenever an application for legalization or special agricultural worker status is denied or the status of a lawful temporary resident is terminated, the alien shall be given written notice setting forth the specific reasons for the denial or termination on Form I-692, Notice of Denial. Form I-692 shall also contain advice to the applicant that he or she may appeal the decision and that such appeal must be taken within 30 days after service of the notification of decision accompanied by any additional new evidence, and a supporting brief if desired. The Form I-692 shall additionally provide a notice to the alien that if he or she fails to file an appeal from the decision, the Form I-692 will serve as a final notice of ineligibility.

(ii) Form I-694, Notice of Appeal, in triplicate, shall be used to file the appeal, and must be accompanied by the appropriate fee. Form I-694 shall be furnished with the notice of denial at the time of service on the alien.

(iii) Upon receipt of an appeal, the administrative record will be forwarded to the Administrative Appeals Unit as provided by § 103.1(f)(2) of this part for review and decision. The decision on the appeal shall be in writing, and if the appeal is dismissed, shall include a final notice of ineligibility. A copy of the decision shall be served upon the applicant and his or her attorney or representative of record. No further administrative appeal shall lie from this decision, nor may the application be filed or reopened before an immigration judge or the Board of Immigration Appeals during exclusion or deportation proceedings.

(iv) Any appeal which is filed that: (A) Fails to state the reason for appeal; (B) is filed solely on the basis of a denial for failure to file the application for adjustment of status under section 210 or 245A in a timely manner; or (C) is patently frivolous, will be summarily dismissed. An appeal received after the thirty (30) day period has tolled will not be accepted for processing.

8. In § 103.4, existing text is redesignated paragraph (a) and a new paragraph (b) is added to read as follows:

§ 103.4 Certifications.

(a) * * *

(b) *Certification of Denials of Special Agricultural Worker and Legalization Applications.* The Regional Processing Facility director may, in accordance with paragraph (a) of this section certify a decision to the Associate Commissioner, Examinations (Administrative Appeals Unit (when the case involves an unusually complex or novel question of law or fact).

9. In § 103.5, existing text is redesignated paragraph (a) and a new paragraph (b) is added to read as follows:

§ 103.5 Reopening or reconsideration.

(a) * * *

(b) *Motions to Reopen or Reconsider Denials of Special Agricultural Worker and Legalization Applications.* The Regional Processing Facility director may *sua sponte* reopen and reconsider any adverse decision when an appeal to the Associate Commissioner, Examinations (Administrative Appeals Unit) has been filed. The director's new decision must be served on the appealing party within 45 days of receipt of any briefs and/or new evidence, or upon expiration of the time allowed for the submission of any briefs.

§ 103.7 [Amended]

10. In § 103.7, paragraph (b)(1) is amended by adding in numerical sequence the following:

Form I-687. For filing application for status as a temporary resident under section 245A (a) of the Immigration and Nationality Act as amended—to be remitted in the form of a cashier's check or money order. A fee of one hundred and eighty-five dollars (\$185.00) for each application or fifty dollars (\$50.00) for each application for a minor child (under 18 years of age) is required at the time of filing with the Immigration and Naturalization Service. The maximum amount payable by a family (husband, wife, and any minor children) shall be four hundred and twenty dollars (\$420.00).

Form I-690. For filing application for waiver of ground of excludability under section 212(a) of the Act as amended, in conjunction with application under sections 210 or 245A of the Act—to be remitted in the form of a cashier's check or a money order, \$35.00.

Form I-694. For appealing the denial of application under sections 210 or 245A of the Act—to be remitted in the form of a cashier's check or a money order, \$50.00.

Form I-695. For filing application for replacement of temporary resident card (Form I-688) under—to be remitted in the form of a cashier's check or a money order, \$15.00.

Form I-698. For filing application for adjustment from temporary resident status to that of lawful permanent resident under section 245A(b)(1) of the Act, as amended—

to be remitted in the form of a cashier's check or money order, (fee amount to be determined as required).

Form I-700. For filing application for status as a temporary resident under section 210(a)(1) of the Act, as amended—to be remitted in the form of a cashier's check or a money order. A fee of one hundred and eighty-five dollars (\$185.00) for each application or fifty dollars (\$50.00) for each application for a minor child (under 18 years of age) is required at the time of filing with the Immigration and Naturalization Service. The maximum amount payable by a family (husband, wife, and any minor children) shall be four hundred and twenty dollars (\$420.00).

PART 211—DOCUMENTARY REQUIREMENTS: IMMIGRANTS; WAIVERS

11. The authority citation for part 211 is revised to read as follows:

Authority: Secs. 101, 103, 211, 212, 223, 235, 247 of the INA, as amended; 8 U.S.C. 1101, 1103, 1181, 1182, 1203, 1225, 1257; Pub. L. 99-603.

12. In § 211.1, paragraph (d) is added to read as follows:

§ 211.1 Visas.

(d) *Returning temporary residents—(I-688).* (1) Form I-688 may be presented in lieu of an immigrant visa by an alien whose status has been adjusted to that of a temporary resident under the provisions of § 210.1 of this chapter, such status not having changed, and who is returning to an unrelinquished residence within one year after a temporary absence abroad.

(2) Form I-688 may be presented in lieu of an immigrant visa by an alien whose status has been adjusted to that of a temporary resident under the provisions of § 245a.2 of this chapter, such status not having changed, and who is returning to an unrelinquished residence within 30 days after a temporary absence abroad, provided that the aggregate of all such absences abroad during the temporary residence period has not exceeded 90 days.

13. In § 211.5, paragraph (d) is added to read as follows:

§ 211.5 Alien commuters.

(d) *Special agricultural workers.* Notwithstanding any other provisions of this part, an alien lawfully admitted for temporary residence under section 210 may commence or continue to reside in foreign contiguous territory and commute to his or her place of employment in the United States to engage in daily or seasonal work which on the whole is regular and stable as provided in section 210(a)(4) of the Act, provided, that at the time of each

reentry a valid Form I-688 is presented in lieu of an immigrant visa and passport. An alien commuter engaged in seasonal work would be presumed to have taken up residence in the United States if he or she is present in this country for more than six months, in the aggregate, during any continuous 12-month period. An alien commuter's address report under section 265 of the Act must show the actual residence address even though it is not in the United States. Temporary resident commuters are subject to loss of commuter status in the same manner as permanent resident commuters as provided in paragraph (b) of this section.

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

14. The authority citation for Part 212 is revised to read as follows:

Authority: Secs. 103, 212 of the INA; as amended; 8 U.S.C. 1103 and 1182; Pub. L. 99-603.

15. In § 212.5, paragraph (b) is amended by removing the period at the end of the last sentence, inserting a semicolon and adding new text to read as set forth below; by redesignating existing paragraph (d)(2) as (d)(2)(i) and adding a new paragraph (d)(2)(ii) to read as follows:

§ 212.5 Parole of aliens into the United States.

(b) * * * however, an alien who arrives at a port of entry and applies for parole into the United States for the sole purpose of seeking adjustment of status under section 245A of the Act, without benefit of advance authorization as described in paragraph (e)(2) of this section shall be denied parole and detained for exclusion in accordance with the provisions of paragraph (b) or (c) of § 235.3 of this chapter. An alien seeking to enter the United States for the sole purpose of applying for adjustment of status under section 210 of the Act shall be denied parole and detained for exclusion under paragraph (b) or (c) of § 235.3 of this chapter.

(d) * * *

(2) * * *

(ii) An alien who is granted parole into the United States after enactment of the Immigration Reform and Control Act of 1986 for other than the specific purpose of applying for adjustment of status under section 245A of the Act shall not be permitted to avail him or herself of the privilege of adjustment

thereunder. Failure to abide by this provision through making such an application will subject the alien to termination of parole status and institution of proceedings under sections 235 and 236 of the Act without the written notice of termination required by § 212.5(d)(2)(i) of this chapter.

PART 234—PHYSICAL AND MENTAL EXAMINATION OF ARRIVING ALIENS

16. The authority citation for Part 234 is revised to read as follows:

Authority: Secs. 103, 234 of the INA as amended; 8 U.S.C. 1103, 1224; Pub. L. 99-603.

§ 234.2 (Amended)

17. In § 234.2, paragraph (b) is amended by inserting the phrase "and local, county and state health departments" immediately after the word "clinic".

PART 242—PROCEEDINGS TO DETERMINE DEPORTABILITY OF ALIENS IN THE UNITED STATES: APPREHENSION, CUSTODY, HEARING, AND APPEAL

18. The authority citation for Part 242 is revised to read:

Authority: Secs. 103, 242, 244, 292 of the INA, as amended; 8 U.S.C. 1101, 1103, 1182, 1252, 1254, 1362; EO 12356; Title 1 of Pub. L. 95-145; Pub. L. 99-603.

19. Section 242.21 is amended by redesignating existing text as paragraph (a) and adding the following new paragraph (b):

§ 242.21 Appeals.

(b) Prohibited appeals; legalization or special agricultural worker applications. An alien respondent defined in § 210.2(f)(3) or (4), 242.13, 243.4, or 245a.2(c)(5), (6), or (7) of this chapter who fails to file an application for adjustment of status to that of a temporary resident within the prescribed thirty-day period, and who is thereafter found to be deportable by decision of an immigration judge, shall not be permitted to appeal the finding of deportability based solely on refusal by the immigration judge to entertain such an application in deportation proceedings.

PART 264—REGISTRATION AND FINGERPRINTING OF ALIENS IN THE UNITED STATES

20. The authority citation for Part 264 is revised to read:

Authority: Secs. 101, 103, 262, 264 of the INA, as amended; 8 U.S.C. 1101, 1103, 1302, 1304; Pub. L. 99-603.

§ 264.1 [Amended]

21. In § 264.1 paragraph (a) is amended by adding at the end of existing text; the following:

I-687 Application for Status as a Temporary Resident—Applicants under section 245A of the Immigration and Nationality Act, as amended.

I-691 Notice of Approval for Status as a Temporary Resident—Aliens adjusted to lawful temporary residence under 8 CFR 210.2 and 245A.2.

I-698 Application to Adjust Status from Temporary to Permanent Resident—Applicants under section 245A of the Immigration and Nationality Act, as amended.

I-700 Application for Status as a Temporary Resident—Applicants under section 210 of the Immigration and Nationality Act, as amended.

22. In 8 CFR 264.1 paragraph (b) is amended by adding at the end of the existing text the following:

I-688 Temporary Resident Card—Lawful temporary residents of the United States.

I-688A Employment Authorization Card.

I-695 Application for Replacement of Form I-688 Temporary Resident Card—While application is pending, aliens whose evidence of registration has been lost, stolen, mutilated, or destroyed; aliens whose original Form I-688 were incorrect when issued.

23. In § 264.1, paragraph (c) is amended by adding the following sentences at the end of the existing text:

(c) * * * Application by an alien lawfully admitted for temporary residence for Form I-688, Temporary Resident Card, in lieu of one lost, stolen, mutilated, or destroyed, shall be made on Form I-695 accompanied by the fee required by § 103.7(b) of this chapter, two color photographs, regardless of the applicant's age, unless the requirement for such photographs has been waived by the director of the legalization office in his or her discretion because of hardship to an applicant who is confined due to age or physical infirmity, and when issuance of Form I-688 is desired in a changed name, by appropriate documentary evidence of such change. Any Form I-688 in the applicant's possession must also be submitted with the application. An application by an alien within the United States for replacement of evidence of registration shall be submitted to the legalization office having jurisdiction over the applicant's place of residence in the United States. Prior to the issuance of Form I-688, all applicants, regardless of age, shall appear at the appropriate legalization office for interview; placement of fingerprint and signature on I-688 unless these requirements are waived at the discretion of the district director.

because of infirmity, illiteracy, or other compelling reasons. An alien who files application Form I-695 may be required to appear in person before an immigration officer prior to the adjudication of the application and be interrogated under oath concerning his or her eligibility for issuance of I-688 as evidence of his or her registration. In addition, the applicant may also be required to present a completed fingerprint card (Form FD-258). The decision on an application for replacement of evidence of registration shall be made by the regional processing facility director having jurisdiction over the alien's place of residence in the United States. No appeal shall lie from the decision of the regional processing facility director denying the application.

PART 299—IMMIGRATION FORMS

24. The authority citation for Part 299 is revised to read as follows:

Authority: Sec. 103 of the INA, as amended; 8 U.S.C. 1103; Pub. L. 99-603.

§ 299.1 (Amended)

25. Section 299.1 is amended by adding the following immediately before the entry "ICAO" in numerical sequence:

I-687 () Application for Status as a Temporary Resident (section 245A INA)

I-688 () Temporary Resident Card

I-688A () Employment Authorization Card

I-690 () Application for Waiver of Grounds of Excludability

I-691 () Notice of Approval of Status as a Temporary Resident

I-692 () Notice of Denial for Status as a Temporary Resident

I-693 () Medical Examination for Status as a Temporary Resident Under Pub. L. 99-603

I-694 () Notice of Appeal

I-695 () Application for Replacement of Form I-688 Temporary Resident Card (Under Pub. L. 99-603)

I-697 () Change of Address

I-698 () Application to Adjust Status from Temporary to Permanent Resident (Under the Immigration Reform and Control Act of 1986)

I-700 () Application for Status as a Temporary Resident (section 210 INA)

I-705 () Affidavit to corroborate employment claimed by an applicant for status as a temporary resident (section 210 INA)

Dated: March 5, 1987.

Alan C. Nelson,

Commissioner.

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8 CFR Part 210**Adjustment of Status for Special Agricultural Workers**

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Proposed rule.

SUMMARY: This rule would create Part 210 of 8 CFR, a new part added to conform with the new section 210 of the Immigration and Nationality Act established by Pub. L. 99-603, the Immigration Reform and Control Act of 1986 (IRCA). This rule sets the criteria and procedures to be used to adjust the status of special agricultural workers to that of temporary residents; sets standards for maintenance of that status and outlines the benefits accruing to temporary residents and the distinctions between temporary and permanent resident status; sets criteria and procedures for termination of temporary resident status; and establishes procedures for adjustment of the status of temporary resident special agricultural workers to that of permanent residents.

DATE: Comments must be received on or before April 20, 1987.

ADDRESS: Send original and two copies of comments to Assistant Commissioner for Legalization, Office of Legalization, Room LL100, 425 I Street, NW., Washington, DC 20536.

FOR FURTHER INFORMATION CONTACT:
William S. Slattery, Assistant Commissioner, Legalization, 425 I Street, NW., Washington, DC 20536, (202) 786-3658.

SUPPLEMENTARY INFORMATION: This proposed rule was drafted in consideration of comments received on a preliminary working draft made available to the public by notice in the *Federal Register* on January 20, 1987. About 6,800 copies of the draft were requested and responses were received from 164 organizations and individuals. The Service appreciates the thoughtfulness and constructive tone of these comments and has adopted many of the suggestions in drafting this proposal.

The IRCA was enacted on November 6, 1986. One of its principal components is a provision for the adjustment of the status of seasonal agricultural workers to that of temporary, and subsequently permanent residents. This provision is designed both to legalize the status of undocumented farmworkers and to ensure that the seasonal labor needs of American growers are met. Therefore any alien who, during the twelve-month period ending on May 1, 1986 performed

agricultural field labor in perishable commodities in the United States for at least 90 man-days, and who is otherwise admissible to the United States, is eligible for adjustment of status as a special agricultural worker.

Although no specific residence requirement for special agricultural worker eligibility is established by the IRCA, both the House-Senate Conference Managers' Report and colloquies on the report in the House and Senate state Congress' clear intent concerning the requirements to be imposed. Based on those sources, Group 2 Special Agricultural Workers are aliens who have both performed 90 man-days of qualifying agricultural employment and resided in the United States for three months in the one-year period ending on May 1, 1986. Group 1 Special Agricultural Workers are aliens who have both engaged in qualifying agricultural employment and resided in the United States for an aggregate period of six months in each of the one-year periods ending on May 1, 1984, 1985, and 1986. Although the Conference Managers' Report refers to a six-month residence requirement for Group 2 workers, both the House and Senate colloquies on the report indicate that this is an error and that a three-month residence requirement was intended; CONG. REC. H10591 (daily ed. October 15, 1986) (remarks of Rep. Panetta, Rep. Rodino, and Rep. Lungren); CONG. REC. S16910 (daily ed. October 17, 1986) (remarks of Sen. Wilson and Sen. Simpson). Satisfaction of the 90 man-day employment requirement constitutes evidence that an applicant has met the three-month residence requirement.

The definition of qualifying employment in this rule is based on the language of section 210(h) of the Immigration and Nationality Act in which "seasonal agricultural services" are defined. The types of employment which are ruled not to be qualifying are inferred from those which are expressly designated as qualifying employment. The definition of the term "man-days" as not less than one hour per day of qualifying agricultural employment conforms to the Fair Labor Standards Act definition and appears consistent with the references in the legislative history to these criteria. Although an application premising eligibility on 90 hours of work over a 90-day period would be highly suspect, the practice of crediting a day on which at least one hour of work was performed as a work day for the purpose of qualification for workers' benefits is based on FLSA precedent and appears applicable here. Defining any day on which piece work

was performed as a "man-day" is based on the Conference Managers' Report.

Although, according to the Conference Managers' Report, an applicant for adjustment of status under this part may meet his or her burden of proof by demonstrating the performance of requisite qualifying employment as a matter of "just and reasonable inference", a mere personal attestation unsupported by corroborating evidence that the applicant performed such employment will not suffice to create such an inference. In the cases cited in the Conference Managers' Report as guidelines for the "just and reasonable inference" standard, the fact of the plaintiffs' employment was clearly demonstrated by evidence of record. The points to be resolved in those cases were the actual or estimated amount of work performed and, consequently, the amount of unpaid compensation owing to the plaintiffs. Based on these cases, in the context of this rule, the "just and reasonable inference" standard can be applied to questions relative to the amount of employment performed but not to the more fundamental question of whether qualifying employment was in fact performed. If an applicant claims to have performed the requisite amount of qualifying employment, but can prove only that he or she performed part of that employment, the "just and reasonable inference" standard is then to be applied to analysis of the evidence actually submitted. This rule also applies this standard to work performed by minors and spouses but credited to a principal family member. An applicant's burden of proof in relation to the required period(s) of residence also is based on these standards.

This rule also provides that all affidavits submitted in evidence must be made under oath and must be accompanied by certified copies of corroborating evidence or contain the affiants' agreement to corroborate their statements if required. These standards are established to conform to the provisions of the IRCA governing the burden of proof of applicants and the prevention and detection of fraud. Provisions for Service verification of other forms of evidence are also established for this reason.

This rule provides that the Service may solicit lists from agricultural producers, farm labor contractors, collective bargaining organizations, and other groups or organizations which maintain records of employment to provide a partial database against which applicants' claims of qualifying employment can be checked. In that the special agricultural worker provisions of

the IRCA are intended to ensure the availability of needed labor for agricultural employers, the Service believes that such employers would be willing to facilitate the process of verifying claimed qualifying employment by providing rosters of former employees.

This rule provides that all documents entered in evidence except certain classes of records must be submitted in the original. It is projected that the special agricultural worker program will encounter a significant fraudulent documents problem. Original documents are required so that they may be subjected to forensic or intelligence analysis if a need for such analysis is indicated.

This rule provides that fees for applications must be submitted in the form of a money order, cashier's check, or bank check and that currency or personal checks will not be accepted.

This rule provides that aliens who have assisted in the persecution of others and those who are nonimmigrant exchange visitors subject to the foreign residence requirement of section 212(e) of the Act who have not satisfied that requirement or received a waiver of it are ineligible for special agricultural worker classification. Though there are no express provisions to this effect in section 210 of the Act, the establishment of these criteria is consistent with the overall scheme of the Immigration and Nationality Act relating to those classes of persons.

This rule contains provisions which interpret the confidentiality and fraud provisions of sections 210(b)(6) and (7) of the Act to permit issuance of an order to show cause and initiation of deportation proceedings against aliens determined as a result of a Service investigation to have engaged in fraud or willful misrepresentation of material facts in applying for status as special agricultural workers. Section 210(b)(6) of the Act permits the use of information furnished in connection with special agricultural worker applications for the purpose of enforcement of the anti-fraud provisions of section 210(b)(7) of the Act. As evidenced by the inclusion of this provision and section 210(b)(7) itself in the IRCA, Congress was concerned with the problem of fraud in special agricultural worker applications and with projections of extensive use of fraudulent or false documents in such applications given the high benefit-risk ratio. Congress intended that vigorous efforts be made to deter, detect, and eliminate such practices. Criminal prosecution alone would be of limited effectiveness in realizing this goal given the procedures and limited resources of

the criminal justice system. Because a significant number of fraudulent attempts are anticipated, it is likely that prosecution will be declined in many cases not due to lack of sufficient evidence or similar deficiencies, but due to the inability of the criminal justice system to process the number of cases generated. The Service interprets section 210(b)(6)(A) of the Act to require enforcement of section 210(b)(7) through deportation proceedings as well as through criminal prosecution.

Temporary residents found to be deportable based on information not protected by the confidentiality provisions can be brought directly into deportation proceedings, just as an alien whose status has been adjusted under section 245 of the Act can be brought into proceedings without his or her status having been rescinded under section 246 of the Act.

Special Agricultural Workers will be temporarily disqualified from certain programs of public assistance to be specified at a later date.

Consular officers at offices designated by the Secretary of State will process and adjudicate applications from aliens abroad under this Part, using the standards established in this Part and following procedures substantially identical with those set forth by INS for processing applications in the United States. Conforming regulations will be promulgated by the Secretary of State in consultation with the Attorney General.

In accordance with 5 U.S.C. 605(b), the Commissioner certifies that this rule if promulgated will not have a significant economic impact on a substantial number of small entities.

This is not a major rule as defined within the meaning of section 1(b) of EO 12291.

The information collection requirements contained in this regulation will be submitted to OMB for review under the Paperwork Reduction Act.

List of Subjects in 8 CFR Part 210

Aliens, Permanent resident status, Reporting and record keeping requirements, Temporary resident status.

Accordingly, it is proposed to amend Chapter I of Title 8 of the Code of Federal Regulations by adding a new Part 210 to read as follows:

PART 210—SPECIAL AGRICULTURAL WORKERS

Sec.

- 210.1 Definition of terms used in this part.
- 210.2 Application for temporary resident status.

Sec.

- 210.3 Eligibility.
- 210.4 Status and benefits.
- 210.5 Adjustment to permanent resident status.

Authority: Pub. L. 99-603, 100 Stat. 3359; 8 U.S.C. 1101 note.

§ 210.1 Definition of terms used in this part.

(a) *Act.* The Immigration and Nationality Act, as amended by the Immigration Reform and Control Act of 1986.

(b) *Application period.* The 18 month period during which an application for adjustment of status to that of a temporary resident may be accepted, beginning on June 1, 1987 and ending on November 30, 1988.

(c) *Complete application.* A complete application consists of an executed Form I-700, Application for Temporary Resident Status as a Special Agricultural Worker, evidence of qualifying agricultural employment and residence, a report of medical examination, the applicant's fingerprints on Form FD-258, and the prescribed number of photographs. An application is not complete until the required fee has been paid and recorded.

(d) *Determination Process.* Determination process as used in this part means reviewing and evaluating all information provided pursuant to an application for the benefit sought and making a determination thereon. If fraud, willful misrepresentation of a material fact, a false writing or document, or any other activity prohibited by section 210(b)(7) of the Act is discovered during the determination process the Service shall refer the case to a U.S. Attorney for possible prosecution and/or issue an Order to Show Cause and Warrant of Arrest.

(e) *Group 1.* Special agricultural workers who have performed qualifying agricultural employment in the United States for at least 90 man-days in the aggregate in each of the twelve-month periods ending on May 1, 1984, 1985, and 1986, and who have resided in the United States for six months in the aggregate in each of those twelve-month periods. The status of a Group 1 temporary resident will be adjusted to that of an alien lawfully admitted for permanent residence as of December 1, 1989.

(f) *Group 2.* Special agricultural workers who during the twelve-month period ending on May 1, 1986 have performed at least 90 man-days in the aggregate of qualifying agricultural employment in the United States. The status of a Group 2 temporary resident

will be adjusted to that of an alien lawfully admitted for permanent residence as of December 1, 1990.

(g) *Legalization Office.* Legalization offices are local offices of the Immigration and Naturalization Service which accept and process applications for legalization or special agricultural workers status, under the authority of the district directors in whose districts such offices are located.

(h) *Man-day.* The term "man-day" means the performance during any day of not less than one hour of qualifying agricultural employment for wages paid. If employment records relating to an alien applicant show only piece rate units completed, then any day in which piece rate work was performed shall be counted as a man-day.

(i) *Nonfrivolous application.* A complete application will be determined to be nonfrivolous at the time the applicant appears for an interview at a legalization office if it contains: (1) evidence or information which shows on its face that the applicant is admissible to the United States or, if inadmissible, that the applicable grounds of excludability may be waived under the provisions of section 210(c)(2)(i) of the Act, and (2) evidence or information which shows on its face that the applicant performed at least 90 man-days of employment in seasonal agricultural services during the twelve-month period from May 1, 1985 through May 1, 1986, and (3) documentation which establishes a reasonable inference of the performance of the seasonal agricultural services claimed by the applicant.

(j) *Other perishable commodities.* [Reserved]

Note.—Regulatory definition will be provided by Department of Agriculture and published by the Immigration and Naturalization Service as an amendment to this regulation.

(k) *Overseas processing office.* Overseas processing offices are offices outside the United States in which, under the authority of the Secretary of State, applications for adjustment to temporary resident status as a special agricultural worker are received, processed, adjudicated, granted or denied, pursuant to regulations or procedures specified by the Secretary of State.

(l) *Public cash assistance.* Public cash assistance means income or needs-based monetary assistance. This includes but is not limited to supplemental security income received by the alien or his immediate family members through federal, state, or local programs designed to meet subsistence

levels. It does not include assistance in kind, such as food stamps, public housing, or other non-cash benefits, nor does it include work-related compensation or certain types of medical assistance (Medicare, emergency treatment, services to pregnant women or children under 18 years of age, or treatment in the interest of public health).

(m) *Qualified designated entity.* A qualified designated entity is any state, local, church, community, or voluntary agency, farm labor organization, association of agricultural employers or individual determined by the Service to be qualified to assist aliens in the preparation of applications for Legalization and/or Special Agricultural Worker status.

(n) *Qualifying agricultural employment.* Qualifying agricultural employment is seasonal field work related to planting, cultural practices, cultivating, growing and harvesting of fruits, vegetables, and other perishable commodities as defined by the Secretary of Agriculture by regulation. Agricultural employment which is not field work (e.g. the sorting or packing of agricultural products at other than a field site, the processing or distribution of agricultural products, equipment maintenance, or administrative duties) is not qualifying employment for the purpose of eligibility for adjustment of status under section 210 of the Act. Field work related to products other than fruits, vegetables, or other perishable commodities is not qualifying employment for the purpose of such eligibility. The requisite period of qualifying agricultural employment depends on whether the alien is applying for Group 1 or Group 2 status.

(o) *Regional processing facility.* Regional Processing Facilities are Service offices established in each of the four Service regions to adjudicate, under the authority of the Directors of the Regional Processing Facilities, applications for adjustment of status under sections 210 and 245a of the Act.

(p) *Service.* The Immigration and Naturalization Service (INS).

(q) *Special agricultural worker.* Any individual granted temporary resident status in the Group 1 or Group 2 classification or permanent resident status under section 210(a) of the Act.

(r) *Subject to an Order to Show Cause.* Subject to an Order to Show Cause means actual service of the Order to Show Cause upon the alien through the mail or by personal service.

§ 210.2 Application for temporary resident status.

(a)(1) *Application for temporary resident status.* An alien agricultural

worker who believes that he or she is eligible for adjustment of status under the provisions of § 210.3 of this part may file an application for such adjustment at a qualified designated entity, at a legalization office, or at an overseas processing office outside the United States. Such application must be filed within the application period except that an alien described in paragraph (b)(2) of this section must file such application during the period(s) specified therein.

(2) *Application for Group 1 status.* An alien who believes that he or she qualifies for Group 1 status as defined in § 210.1(d) of this part and who desires to apply for that classification must so endorse his or her application at the time of filing. Applications not so endorsed will be regarded as applications for Group 2 status as defined in § 210.1(e) of this part.

(3) *Numerical limitations.* The numerical limitations of sections 201 and 202 of the Act do not apply to the adjustment of aliens to lawful temporary or permanent resident status under section 210 of the Act. No more than 350,000 aliens may be granted temporary resident status in the Group 1 classification. If more than 350,000 aliens are determined to be eligible for Group 1 classification, the first 350,000 aliens who file applications for that classification shall be accorded that classification upon approval of their applications. Applicants who may be eligible for Group 1 classification who file after the first 350,000 applications have been received shall be classified as Group 2 aliens. There is no limitation on the number of aliens whose resident status may be adjusted from temporary to permanent in Group 2 classification.

(b) *Filing date of application—(1) General.* The date the alien submits an application to a qualified designated entity, legalization office or overseas processing office shall be considered the filing date of the application, provided that in the case of an application filed at a qualified designated entity the alien has consented to have the entity forward the application to a legalization office. Qualified designated entities are required to forward completed applications to the appropriate legalization office within 60 days after receipt. Except as provided in paragraph (a)(2) of this section, applications must be filed no later than November 30, 1988.

(2) *Filing date for eligible aliens apprehended prior to the application period.* An alien who was apprehended by the Service on or after November 6, 1986 and prior to June 1, 1987 and who has established a nonfrivolous claim to eligibility for adjustment of status under

section 210 of the Act must file an application for adjustment of status during the period beginning on June 1, 1987 and ending on June 30, 1987.

(c) *Filing of application*—(1) *General*. The application must be filed on Form I-700 at a qualified designated entity, at a legalization office, or at an overseas processing office. Only aliens who entered before November 6, 1986 and remained in the United States, other than during a period of travel authorized by the Service, may file applications in the United States. All other aliens seeking adjustment of status under this part must file applications for that benefit outside the United States. If the applicant is 14 years or older, the application must be accompanied by a completed Form FD-258 (Fingerprint Card).

(2) *Applications in the United States*. (i) In the case of applications filed at a Service legalization office, the district director, at his or her discretion, may require filing either by mail or in person, or may permit filing in either manner. The applicant must appear for a personal interview at the legalization office when scheduled.

(ii) All fees for applications filed in the United States must be submitted in the exact amount in the form of a money order, cashier's check, or bank check made payable to the Immigration and Naturalization Service. No personal checks or currency will be accepted. Fees will not be waived or refunded under any circumstances.

(3) *Applications outside the United States*. An application for temporary residence under this part filed by an alien outside the United States must be filed with the required fee at an overseas processing office. Consular officers at overseas processing offices are authorized to approve or deny such applications.

(d) *Interview*. Each applicant, regardless of age, must appear at the appropriate Service legalization office or overseas processing office and must be fingerprinted for the purpose of issuance of Form I-688. Each applicant shall be interviewed by an immigration or consular officer, except that the interview may be waived when it is impractical because of the health of the applicant.

(e) *Medical examination*. An applicant under this part shall be required to be examined by a selected civil surgeon or, in the case of an applicant abroad, by a physician or clinic designated to perform medical examinations of immigrant visa applicants, whose report setting forth the findings concerning the mental and physical condition of the applicant shall

be incorporated into the record. Any applicant certified as excludable under paragraphs (1), (2), (3), (4), or (5) of section 212(a) of the Act may appeal to a Board of Medical Officers of the U.S. Public Health Service as provided in section 234 of the Act and Part 235 of this chapter.

(f) *Limitation on access to information and confidentiality*. (1) Except for consular officials engaged in the processing of applications overseas and employees of a qualified designated entity where an application is filed with that entity, no person other than a sworn officer or employee of the Department of Justice or bureau or agency thereof, will be permitted to examine individual applications.

(2) Files and records prepared by qualified designated entities under this section are confidential. The Attorney General and the Service shall not have access to these files and records without the consent of the alien.

(3) Information furnished pursuant to an application for temporary resident status under this section shall only be used in the determination process or to enforce the provisions of section 210(b)(7) of the Act, relating to fraud and false statements in applications as provided in paragraph (f)(4) of this section.

(4) If a determination is made by the Service that the alien has, in connection with his or her application, engaged in fraud or willful misrepresentation of a material fact, provided a false writing or document in making his or her application, or engaged in any other activity prohibited by section 210(b)(7) of the Act, the Service shall refer the matter to the U.S. Attorney for possible prosecution of the alien or any person who created or supplied a false writing or document for use in an application for adjustment of status under this part. If prosecution is declined, the Service may issue an order to show cause and warrant of arrest, unless the United States Attorney has notified the Service that the matter submitted is without merit.

(g) *Decision*. The applicant shall be notified of the decision and, if the application is denied, of the reason therefor. Appeal from an adverse decision under this part may be taken by the applicant on Form I-894, in accordance with the provisions of § 103.3(a)(2) of this chapter. An applicant for Group 1 status as defined in § 210.1(e) of this part who is determined to be ineligible for that status may be classified as a temporary resident eligible for permanent residence under Group 2 as defined in § 210.1(f) of this part if otherwise

eligible for Group 2 status. In such a case the applicant shall be notified of the decision to accord him or her Group 2 status and to deny Group 1 status. He or she is entitled to file an appeal in accordance with the provisions of § 103.3(a)(2) of this chapter from that portion of the decision denying Group 1 status.

(h) *Motions*. The regional processing facility director may *sua sponte* reopen and reconsider any adverse decision. When an appeal to the Associate Commissioner, Examinations (Administrative Appeals Unit) has been filed, the INS director of the Regional Processing Facility may issue a new decision that will grant the benefit which has been requested. The director's decision must be served on the appealing party within forty-five (45) days of receipt of any briefs and/or new evidence, or upon expiration of the time allowed for the submission of any briefs.

(i) *Certifications*. The regional processing facility director may, in accordance with § 103.4 of this chapter, certify a decision to the Associate Commissioner, Examinations (Administrative Appeals Unit) when the case involves an unusually complex or novel question of law or fact.

§ 210.3 Eligibility.

(a) *General*. An alien who, during the twelve-month period ending on May 1, 1986, has both engaged in qualifying agricultural employment in the United States for at least 90 man-days is eligible for status as an alien lawfully admitted for temporary residence if otherwise admissible under the provisions of section 210(c) of the Act and if he or she is not ineligible under the provisions of paragraph (d) of this section.

(b) *Proof of eligibility*—(1) *Burden of proof*. An alien applying for adjustment of status under this part has the burden of proving by a preponderance of the evidence that he or she has worked the requisite number of man-days, and in the case of a Group 1 applicant, has resided in the United States for the requisite periods, is admissible to the United States under the provisions of section 210(c) of the Act, and is otherwise eligible for adjustment of status under this section. If the applicant cannot provide documentation which shows qualifying employment for each of the requisite man-days, or in the case of a Group 1 applicant, which meets the residence requirement, the applicant may meet his or her burden of proof by providing documentation sufficient to establish the requisite employment or residence as a matter of just and

reasonable inference. The inference to be drawn from the documentation provided shall depend on the extent of the documentation, its credibility and amenability to verification as set forth in paragraphs (d) (2) and (3) of this section.

(2) **Evidence.** The sufficiency of all evidence produced by the applicant will be judged according to its probative value and credibility. Original documents will be given greater weight than copies. To meet his or her burden or proof, an applicant must provide evidence of eligibility apart from his or her own testimony. Analysis of evidence submitted will include consideration of the fact that work performed by minors and spouses is sometimes credited to a principal member of a family.

(3) **Verification.** Affidavits and other personal testimony by an applicant which are not corroborated, in whole or in part, by other credible evidence (including testimony of persons other than the applicant) will not serve to meet an applicant's burden of proof. All evidence of identity, qualifying employment, admissibility, and eligibility submitted by an applicant for adjustment of status under this part will be subject to verification by the Service. Failure by an applicant to release information protected by the Privacy Act or related laws when such information is essential to the proper adjudication of an application may result in denial of the benefit sought. The Service may solicit from agricultural producers, farm labor contractors, collective bargaining organizations and other groups or organizations which maintain records of employment, lists of workers against which evidence of qualifying employment can be checked. If such corroborating evidence is not available and the evidence provided is deemed insufficient, the application may be denied.

(c) **Documents.** A complete application for adjustment of status filed under this part must be accompanied by proof of identity, evidence of qualifying employment, evidence of residence and such evidence of admissibility or eligibility as is required hereunder and as may be requested by the examining immigration officer in accordance with such requirement. Wherever possible documents must be submitted in the original except the following: Official government records, employment or employment related records maintained by employers, unions, or collective bargaining organizations; school records maintained by a school or school board; or other records maintained by a party other than the applicant. Copies of

records maintained by parties other than the applicant which are submitted in evidence must be certified as true and correct by such parties and must bear their seal or signature or the signature and title of persons authorized to act in their behalf. If the return of original documents is desired by the applicant, they must be accompanied by notarized copies or copies certified true and correct by a qualified designated entity or by the alien's representative in the format prescribed in § 204.2(j)(1) or (2) of this chapter. Such certified copies unaccompanied by original documents are unacceptable for the purposes of an application under this part. At the discretion of the district director or consular officer, original documents, even if accompanied by certified copies, may be temporarily retained for forensic examination.

(1) **Proof of identity.** Evidence to establish identity is listed below in descending order of preference:

- (i) Passport;
- (ii) Birth certificate;
- (iii) Any national identity document from a foreign country bearing a photo and/or fingerprint (e.g., "cedula", "cartilla", "carte d'identite," etc.);
- (iv) Driver's license or similar document issued by a state if it contains a photo;
- (v) Baptismal record or marriage certificate; or
- (vi) Affidavits.

(2) **Assumed names—(i) General.** In cases where an applicant claims to have met any of the eligibility criteria under an assumed name, the applicant has the burden of proving that the applicant was in fact the person who used that name.

(ii) **Proof of common identity.** The most persuasive evidence is a document issued in the assumed name which identifies the applicant by photograph, fingerprint or detailed physical description. Other evidence which will be considered are affidavit(s) by a person or persons other than the applicant, made under oath, which identify the affiant by name and address, state the affiant's relationship to the applicant and the basis of the affiant's knowledge of the applicant's use of the assumed name. Affidavits accompanied by a photograph which has been identified by the affiant as the individual known to the affiant under the assumed name in question will carry greater weight. Other documents using the assumed name which are in the possession of the applicant may serve to establish the common identity when substantiated by corroborating detail.

(3) **Proof of employment.** The applicant may establish qualifying

employment by primary evidence, or where such primary evidence is not reasonably available, by secondary evidence, or by a combination of the two.

(i) **Primary evidence.** An applicant may establish the performance of qualifying employment through government employment records or records maintained by agricultural producers, farm labor contractors, collective bargaining organizations and other groups or organizations which maintain records of employment.

(ii) **Secondary evidence.** If primary evidence of qualifying employment is not reasonably available to the applicant, or if the primary evidence does not provide complete information with respect to employment, the applicant may submit any other evidence which may tend to corroborate performance of qualifying employment. Such secondary evidence includes but is not limited to worker identification issued by employers or collective bargaining organizations, union membership cards or other union records such as dues receipts or records of the applicant's involvement or that of his or her immediate family with organizations providing services to farmworkers. Also included are work records such as pay stubs, piece work receipts, W-2 Forms or copies of income tax returns certified by the IRS.

Affidavits may be submitted under oath, by agricultural producers, foremen, farm labor contractors, fellow employees, or other persons with specific knowledge of the applicant's employment. The affiant must be identified by name and address; the name of the applicant and the relationship of the affiant to the applicant must be stated; and the source of the information in the affidavit (e.g. personal knowledge, reliance on information provided by others, etc.) must be indicated. The affidavit must also provide information regarding the crop and the type of work performed by the applicant and the period during which such work was performed. The affiant must provide a certified copy of corroborating records or state the affiant's willingness to personally verify the information provided. The weight and probative value of any affidavit accepted will be determined on the basis of the substance of the affidavit and any documents which may be affixed thereto which may corroborate the information provided.

(4) **Proof of residence.** Evidence to establish residence in the United States during the requisite period(s) includes: Employment records as described in paragraph (c)(3) of this section; utility

bills (gas, electric, phone, etc.), receipts, or letters from companies showing the dates during which the applicant received service; school records (letters, report cards, etc.) from the schools that the applicant or his or her children have attended in the United States showing the name of school, name and, if available, address of student, and periods of attendance, and hospital or medical records showing similar information; attestations by churches, unions, or other organizations to the applicant's residence by letter which identify applicant by name, are signed by an official (whose title is shown), show inclusive dates of membership, state the address where applicant resided during the membership period, include the seal of the organization impressed on the letter, establish how the author knows the applicant, and the origin of the information; and additional documents that could show that the applicant was in the United States at a specific time, such as: money order receipts for money sent out of the country; passport entries; birth certificates of children born in the United States; bank books with dated transactions; letters of correspondence between the applicant and another person or organization; Social Security card; Selective Service card; automobile license receipts, title, vehicle registration, etc.; deeds, mortgages, contracts to which applicant has been a party; tax receipts; insurance policies, receipts, or letters; and any other document that will show that applicant was in the United States at a specific time. For Group 2 eligibility, evidence of performance of the required 90 man-days of seasonal agricultural services shall constitute evidence of qualifying residence.

(5) *Proof of financial responsibility.* Generally, the evidence of employment submitted under paragraph (c)(3) of this section will serve to demonstrate the alien's financial responsibility. If it appears that the applicant may be inadmissible under section 212(a)(15) of the Act, he or she may be required to submit documentation showing a history of employment without reliance on public cash assistance for all periods of residence in the United States.

(d) *Ineligible classes.* The following classes of aliens are ineligible for temporary residence under this part:

(1) An alien who has assisted in the persecution of any person or persons on account of race, religion, nationality, membership in a particular social group, or political opinion;

(2) An alien who at any time was a nonimmigrant exchange visitor under section 101(a)(15)(J) of the Act who is

subject to the two-year foreign residence requirement unless the alien has complied with that requirement or the requirement has been waived pursuant to the provisions of section 212(e) of the Act.;

(3) An alien who was in the custody of the Service or was apprehended as a deportable alien after November 6, 1986 and prior to June 1, 1987 who was determined to have a nonfrivolous claim to eligibility for adjustment of status under the provisions of section 210(d)(1) of the Act and who does not file an application for adjustment of status to that of temporary resident under this part prior to July 1, 1987;

(4) An alien who was apprehended as a deportable alien subsequent to the beginning of the application period on June 1, 1987 who does not file an application for adjustment of status to that of temporary resident under this part prior to the thirty-first day after his or her release from Service custody or December 1, 1988, whichever is earlier.

(5) An alien excludable under the provisions of section 212(a) of the Act whose grounds of excludability may not be waived, pursuant to section 210(c)(2)(B)(ii) of the Act.

(e) *Exclusion grounds—(1) Grounds of exclusion not to be applied.* Sections (14), (20), (21), (25), and (32) of section 212(a) of the Act shall not apply to applicants applying for temporary resident status.

(2) *Waiver of grounds for exclusion.* Except as provided in paragraph (c)(3) of this section, the Attorney General or the Secretary of State, if the application is filed overseas, may waive any other provision of section 212(a) of the Act only in the case of individual aliens for humanitarian purposes, to assure family unity, or when the granting of such a waiver is in the public interest. If an alien is excludable on grounds which may be waived as set forth in this paragraph, he or she shall be advised of the procedures for applying for a waiver of grounds of excludability on Form I-690. When an application for waiver of grounds of excludability is filed jointly with an application for temporary residence under this section, it shall be accepted for processing at the legalization office or overseas

processing office. If an application for waiver of grounds of excludability is submitted after the alien's preliminary interview at the legalization office it shall be forwarded to the appropriate regional processing facility. All applications for waivers of grounds of excludability must be accompanied by the correct fee in the exact amount. All fees for applications filed in the United States must be in the form of a money

order, cashier's check, or bank check. No personal checks or currency will be accepted. Fees will not be waived or refunded under any circumstances. An application for waiver of grounds of excludability under this part submitted at a legalization office shall be approved or denied by the director of the regional processing facility in whose jurisdiction the applicant's application for adjustment of status was filed, except that in cases involving clear statutory ineligibility or admitted fraud, such application may be denied by the district director in whose jurisdiction the application is filed, and in cases returned to a legalization office for reinterview, such application may be approved at the discretion of the district director. The applicant shall be notified of the decision and, if the application is denied, of the reason therefor. The applicant may appeal the decision within 30 days after the service of the notice pursuant to the provisions of § 103.3(a) of this chapter.

(3) *Grounds of exclusion that may not be waived.* The following provisions of section 212(a) of the Act may not be waived:

(i) Paragraphs (9) and (10) (criminals);
 (ii) Paragraph (15) (public charge) except as provided in paragraph (c)(4) of this section.

(iii) Paragraph (23) (narcotics) except for a single offense of simple possession of thirty grams or less of marijuana.

(iv) Paragraphs (27), (prejudicial to the public interest), (28), (communists), and (29) (subversive);

(v) Paragraph (33) (nazi persecution).

(4) *Special rule for determination of public charge.* An alien is not excludable under paragraph (c)(3)(ii) of the section if the alien demonstrates a history of employment in the United States evidencing self-support without reliance on public cash assistance as defined in § 210.1(l) of this part.

§ 210.4 Status and benefits.

(a) *Date of adjustment.* The status of an alien whose application for temporary resident status is approved shall be adjusted to that of a lawful temporary resident as of the date on which the fee was paid at a legalization office, except that the status of an alien who applied for such status at an overseas processing office shall be adjusted as of the date of his or her entry into the United States after approval of his or her application.

(b) *Employment and travel authorization—(1) General.*

Authorization for employment and travel abroad for temporary resident status applicants under section 210 of

the Act may only be granted by a Service legalization office. In the case of an application which has been filed with a qualified designated entity, employment authorization may only be granted after a nonfrivolous application has been received at a legalization office, and receipt of the fee has been recorded.

(2) *Employment authorization prior to the granting of temporary resident status.* Permission to travel abroad and to accept employment will be granted to the applicant, after an interview has been conducted in connection with a nonfrivolous application at a legalization office. If an interview appointment cannot be scheduled within 30 days from the date an application is filed at a legalization office, authorization to accept employment will be granted valid to the scheduled appointment date. The appointment letter will be endorsed with the temporary employment authorization. Employment authorization subsequent to an interview will be granted on Service Form I-688A, and will be restricted to six months duration, pending final determination on the application for temporary resident status. If a final determination has not been made on the application prior to the expiration date of the I-688A, that date may be extended upon return of the I-688A by the applicant to the legalization office where it was obtained.

(3) *Employment and travel authorization upon grant of temporary resident status.* Upon grant of an application for adjustment to temporary resident status by a regional processing facility, the processing facility will forward a notice of approval to the applicant at his or her last known address and to his or her qualified designated entity or representative. The applicant will be required to return to the legalization office where the application was initially received, surrender the I-688A previously issued, and will be issued Form I-688, Temporary Resident Card, authorizing employment and travel abroad. An alien whose status is adjusted to that of a lawful temporary resident under section 210 of the Act has the right to reside in the United States, to travel abroad (including commuting from a residence abroad), and to accept employment in the United States in the same manner as aliens lawfully admitted for permanent residence.

(c) *Ineligibility for immigration benefits.* An alien whose status is adjusted to that of a lawful temporary resident under section 210 of the Act is

not entitled to submit a petition pursuant to section 203(a)(2) or to any other benefit or consideration accorded under the Act to aliens lawfully admitted for permanent residence, except as provided in paragraph (b)(3) of this section.

(d) *Termination of temporary resident status—(1) General.* The Director of the regional processing facility may terminate the temporary residence status of a special agricultural worker at any time in accordance with section 210(a)(3) of the Act if the alien is determined to be deportable under section 241 of the Act. An alien who is excludable under section 210(c) of the Act, who is not deportable under section 241 of the Act, is not subject to termination of temporary resident status if the ground of excludability arose subsequent to the adjustment of the alien's status to that of a temporary resident. The termination of an alien's temporary residence status may be based on a finding by a district director that the alien is deportable. It is not necessary that a final order of deportation have been entered in order to terminate temporary resident status.

(2) *Procedure.* The termination of an alien's status under paragraph (d)(1) of this section will be made only on notice to the alien, who shall be afforded an opportunity to offer evidence in opposition to the grounds alleged for termination of his or her status. If the alien is deportable under section 241(a)(10) of the Act because he or she was excludable at the time of his or her adjustment of status to that of lawful temporary resident, he or she shall be advised of the procedures for applying for a waiver of grounds of excludability on Form I-690 if a waiver is available under section 210(c) of the Act. If the alien is granted such a waiver, the Service proceeding to terminate the alien's lawful temporary resident status will be concluded, and the alien will be so advised.

If the alien's status is terminated, the director of the Regional Processing Facility shall notify the alien of the decision and of the reasons for the termination. The alien may appeal the decision within 30 days after the service of the notice, pursuant to the provisions of § 103.3(a)(2) of this part.

(3) *Surrender of Form I-688.* An alien whose status as a temporary resident has been terminated under this section shall, upon demand, promptly surrender to the district director having jurisdiction over the alien's place of residence or, in the case of a commuter, employment, the Form I-688, Temporary Resident Card, issued to him or her at

the time of the grant of temporary resident status.

§ 210.5 Adjustment to permanent resident status.

(a) *Eligibility and date of adjustment to permanent resident status.* The status of an alien lawfully admitted to the United States for temporary residence under section 210(a)(1) of the Act, if the alien has otherwise maintained such status as required by the Act, shall be adjusted to that of an alien lawfully admitted to the United States for permanent residence as of the following dates:

(1) *Group 1.* The status of an alien determined to be eligible for Group 1 classification shall be adjusted to that of an alien lawfully admitted for permanent residence as of December 1, 1989.

(2) *Group 2.* The status of an alien determined to be eligible for Group 2 classification shall be adjusted to that of an alien lawfully admitted for permanent residence as of December 1, 1990.

(b) *Maintenance of temporary resident status; ADIT processing—(1) General.* Before the status of an alien lawfully admitted for temporary residence under section 210(a)(1) of the Act can be adjusted to that of an alien lawfully admitted for permanent residence, the alien must appear at a legalization office or such other Service office as is designated for this purpose for a determination that he or she has maintained temporary resident status, and for completion of processing for issuance of Form I-551, Alien Registration Receipt Card.

(2) *Maintenance of status.* Information provided by the alien concerning his or her maintenance of status will be subject to Service verification. The status of an alien described in paragraph (b)(1) of this section who has maintained temporary resident status will be adjusted to that of an alien lawfully admitted for permanent residence effective on the date appropriate for his or her group as provided in paragraph (a) of this section. The alien must execute an affidavit stating that he or she has maintained status as a temporary resident. An alien who is deportable under section 241 of the Act has failed to maintain status as a temporary resident and is subject to termination of temporary resident status as provided in § 210.4(d) of this part. An alien who is excludable under section 210(c) of the Act who is not deportable under section 241 of the Act is not subject to termination of temporary resident status if the ground of

excludability arose subsequent to the adjustment of the alien's status to that of a temporary resident. If the alien is deportable under section 241(a) of the Act because he or she was excludable at the time his or her status was adjusted to that of a lawful temporary resident, he or she shall be advised of the procedures for applying for a waiver of grounds of excludability if a waiver is available under section 210(c) of the Act. If the alien applies for such a waiver, and the waiver is granted after the dates of adjustment set in paragraph (a) of this section, the adjustment of the alien's status to that of an alien lawfully admitted for permanent residence shall be recorded as of the date of adjustment appropriate for his or her group.

(3) *ADIT processing.* An alien described in paragraph (b)(1) of this section must provide suitable ADIT photographs, and a fingerprint and signature must be obtained from the alien on Form I-89.

Dated: March 5, 1987.

Alan C. Nelson,

Commissioner, Immigration and
Naturalization Service.

[FIR Doc. 87-5837 Filed 3-17-87; 10:10 am]

BILLING CODE 4410-10-M

8 CFR Part 245a

Adjustment of Status for Certain Aliens

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This rule would implement section 245A of the Immigration and Nationality Act as amended by section 201 of the Immigration Reform and Control Act of 1986 ("IRCA"). Section 201 of IRCA directs the Attorney General to adjust the status of certain aliens to that of aliens lawfully admitted for temporary residence if they meet certain requirements. This section also directs the Attorney General to adjust the status of a temporary resident alien to that of an alien lawfully admitted for permanent residence if the alien meets certain requirements.

DATE: Comments must be received on or before April 20, 1987.

ADDRESS: Send original and two copies of comments to Assistant Commissioner for Legalization, Office of Legalization, Room LL-100, INS, 425 "I" Street NW., Washington, DC 20536.

FOR FURTHER INFORMATION CONTACT:
William S. Slattery, Assistant
Commissioner, Legalization, 425 "I"

Street NW., Washington, DC 20536, (202) 786-3658.

SUPPLEMENTARY INFORMATION:

Background of Proposed Rule

On November 6, 1986, the President signed into law the Immigration Reform and Control Act of 1986, Pub. L. 99-603 ("IRCA"). This legislation is the most comprehensive reform of our immigration laws since the enactment of the Immigration and Nationality Act ("INA") in 1952. This legislation reflects a resolve to strengthen law enforcement to control illegal immigration. It also reflects the Nation's humanitarian concerns for certain aliens who have been residing illegally in the United States. The theme of this legislation is that the key to maintaining the immigration tradition of the United States is the firm, fair enforcement of laws, which are designed to encourage the continued flow of legal immigrants, and to close the back door to illegal entry.

Section 201 of IRCA, the subject of this proposed rule, reflects the traditional humanitarian concerns of this Nation by providing for the legalization of status of certain aliens who have been residing illegally in the United States since January 1, 1982. At the same time, as reflected under certain provisions of section 201 of IRCA, Congress intended that aliens eligible for the legalization program be admissible as immigrants, therefore requiring the aliens to meet certain standards of eligibility.

Since November 6, 1986, the Immigration and Naturalization Service has taken a number of steps to insure that the new legislation will be implemented effectively, fairly, and in an orderly manner. Service officials have engaged in a continuing dialogue with members of the public and representatives of interested organizations on how to implement this legislation. On January 20, 1987, the Service took the unprecedented step of publishing in the *Federal Register* a notice making available to the public the preliminary working draft regulations. More than 6,800 persons requested and received a copy of these preliminary draft regulations. As a result, 164 individuals and interested organizations submitted written comments. All comments were seriously considered by the Service. A number of the suggestions received by the Service are reflected in this proposed rule.

These rules implementing section 201 of IRCA are proposed against this background of openness and a good-faith on the part of the Service to maintain an ongoing dialogue.

Summary of the Proposed Rule

The proposed rule would amend 8 CFR Part 245 by creating a new Part 245a. The proposed rule would permit certain aliens, who are otherwise eligible, to adjust their status to that of aliens lawfully admitted for temporary residence.

Aliens who are eligible to apply include: Aliens who entered the United States before January 1, 1982 and who have continued to reside in the United States in an unlawful status since such date and through the date the alien files an application under this rule; aliens who entered the United States prior to January 1, 1982 as nonimmigrants and whose period of authorized stay expired before January 1, 1982 or whose unlawful status was known to INS as of such date; aliens whose status is that of Cuban-Haitian Entrants; and, aliens who prior to January 1, 1982 were either granted extended voluntary departure (EVD) or were in a deferred action status.

All applicants for legalization, with certain exceptions for those applicants who have a Cuban-Haitian Entrant status, must meet certain requirements. In general, an applicant must establish, (1) continuous residence in the United States since January 1, 1982; (2) continuous physical presence in the United States since November 6, 1986; and (3) admissibility as an immigrant. Additionally, applicants must file a timely application as prescribed under this rule, submit the result of a prescribed medical examination and provide proof that they either have registered or are registering under the Military Selective Service Act, if required to be so registered under that Act.

This rule establishes a single level of appellate review to permit the applicant to challenge a denial of his application for temporary resident status. This rule also provides that that status shall be terminated by the Service upon the occurrence of certain events.

This rule also sets forth procedures and the substantive requirements for the adjustment of status of temporary residents to that of permanent residents.

Finally, the rule provides that aliens who submit false documentation or make false representations in support of their application for legalization will be subject to criminal prosecution and eventual expulsion from the United States.

Key Provisions of the Proposed Rule

Application Period: An alien must file an application for legalization between

May 5, 1987 and May 4, 1988. However, aliens who have been served with an Order to Show Cause subsequent to November 6, 1986, must apply within thirty days of the beginning of the application period. Aliens who are served with an Order to Show Cause during the application period must apply within thirty days but not later than May 4, 1988. Failure to apply within the application period, as fully set forth in this rule, will render the alien statutorily ineligible for legalization.

Where to File the Application: Form I-687 () and supporting documentation may be filed either at a Service Legalization Office or with a Qualified Designated Entity ("ODE").

What Documentation Should be Submitted to INS: In addition to the completed Form I-687, the applicant must submit the result of a medical examination, an application for waivers of grounds of excludability, if applicable, and sufficient documentary information as fully set forth in this rule, to prove the applicant's identity, his or her continuous residence in the United States since January 1, 1982, and proof of financial responsibility. The Service advises eligible aliens to start gathering this documentation as soon as possible.

Eligibility Requirements

(1) Continuous Residence Since January 1, 1982

An applicant otherwise eligible for legalization must prove that he or she "resided continuously" in the United States since January 1, 1982. However, certain absences will not be considered to have interrupted this continuous residence requirement. The Service initially considered that a single absence of more than 30 days or aggregate absences totaling more than 150 days would break the continuous residence requirement. However, in light of the public comments received on this subject, the Service has reconsidered its position and under the proposed rule a single absence of 45 days or more and aggregate absences of 180 days or more would break the continuous residence requirement.

(2) Continuous Physical Presence Since November 6, 1986

In addition to the continuous residence requirement since January 1, 1982, the applicant must prove that he has been continuously physically present in the United States since November 6, 1986. Under the proposed rule, absences that were brief, casual, and innocent will not break the physical presence requirement. Only an absence authorized by the Service for not more

than thirty (30) days will be considered brief, casual, and innocent. An alien who entered the United States without inspection subsequent to November 6, 1986, will not be considered to have made an "innocent" absence. The INA imposes criminal penalties on aliens who enter the United States without inspection. Section 201 of IRCA was enacted to forgive certain past illegalities and not subsequent violations of our laws.

(3) Definition of the Term "Known to the Government"

An alien who entered the United States as a nonimmigrant before January 1, 1982, may be eligible for legalization if the alien's "unlawful status was known to the Government" as of January 1, 1982. The Service, in this proposed rule, is interpreting the term "known to the Government" to mean "INS." This interpretation as previously set forth in the preliminary draft regulations, was challenged by many commentators. The Service initially proposed that an alien's unlawful status would have been known by the Service, if the Service had made an affirmative determination that the alien was subject to deportation proceedings. In light of the public comments, the Service has reconsidered its initial proposal. Under this proposed rule, if the Service received information as of January 1, 1982 from a federal agency reflecting the fact that the alien clearly expressed to the federal agency that he or she was in violation of his or her lawful status, and that information is contained in the alien's A File, the alien's unlawful status would be known to INS regardless of whether or not the Service made a determination that the alien was subject to deportation proceedings.

Pursuant to section 103 of the INA, only the Attorney General is charged with the administration and enforcement of the immigration laws. Correspondingly, only the Attorney General can make a determination that an alien's status is "unlawful." To interpret the word "Government" to include Federal, State, and local agencies would make the administration of section 201 difficult, if not impossible, and would implicitly vest government agencies with an authority that Congress specifically granted only to the Attorney General.

(4) Admissible as an Immigrant

An alien who meets the residence requirements must be admissible as an immigrant. This rule implements the statutory requirements that certain grounds of admissibility are not applicable, that other grounds may be

waived, and that other grounds cannot be waived. This rule also defines the terms "felony" and "misdemeanor." The term "felony" is defined as including a felony committed outside the United States. This rule also sets forth procedures for obtaining waivers of those grounds of admissibility which may be waived. In determining a waiver based on "family unity" the proposed rule defines family unity as limited to spouses, unmarried minor children and parents.

Administrative Appellate Review

This proposed rule establishes a single level of administrative appellate review to adjudicate appeals from legalization decisions. The proposed appellate authority is the Associate Commissioner for Examinations.

Termination of Temporary Resident Status

Consistent with section 245A(b)(2) of IRCA, this proposed rule sets forth the procedural and substantive grounds for terminating the status of a temporary resident alien. The rule proposes that a decision to terminate status may be appealed to the Associate Commissioner for Examinations.

Adjustment of Temporary Resident Status to Permanent Resident Status

This rule sets forth the proposed procedural and substantive requirements that a temporary resident alien must comply with in order to change his or her status to that of an alien lawfully admitted for permanent residence. This rule proposes to eliminate the requirement of a second medical examination to the extent that all applicants for temporary residents must submit to a medical examination.

Temporary Disqualification of Newly Legalized Aliens From Receiving Certain Public Welfare Assistance

The Attorney General will publish a separate list of programs identified as programs of financial assistance furnished under Federal law (whether through grant, loan, guarantee, or otherwise) on the basis of financial need which newly legalized aliens (with limited exceptions) may not receive for five (5) years.

In accordance with 5 U.S.C. 605(b), the Commissioner of Immigration and Naturalization Service certifies that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

This is not a major rule as defined within the meaning of section 1(b) of EO 12291.

The information collection requirements contained in this regulation will be submitted to OMB for review under the Paperwork Reduction Act.

List of Subjects in 8 CFR Part 245a

Aliens, Temporary resident status and permanent resident status.

Proposed Rule

Accordingly, pursuant to the Immigration Reform and Control Act of 1986, and section 103 of the Immigration and Nationality Act, as amended, the Immigration and Naturalization Service proposes to add a new Part 245a in Title 8, Code of the Federal Regulations to be known as 8 CFR Part 245a. Part 245a is proposed to read as follows:

PART 245a—ADJUSTMENT OF STATUS TO THAT OF PERSONS ADMITTED FOR LAWFUL TEMPORARY OR PERMANENT RESIDENT STATUS UNDER SECTION 245A OF THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED BY PUB. L. 99-603, THE IMMIGRATION REFORM AND CONTROL ACT OF 1986

Sec.

245a.1 Definitions.

245a.2 Application for temporary residence.

245a.3 Application for adjustment of status from temporary to permanent resident.

Authority: Pub. L. 99-603, 100 Stat. 3359; 8 U.S.C. 1101 note.

§ 245a.1 Definitions.

As used in this chapter:

(a) The term "Act" means the Immigration and Nationality Act, as amended by The Immigration Reform and Control Act of 1986.

(b) The term "Service" means the Immigration and Naturalization Service (INS).

(c)(1) The term "resided continuously" as used in section 245A(a)(2) of the Act, means that the alien shall be regarded as having resided continuously in the United States if, at the time of filing of the application for temporary resident status: (i) No single absences from the United States has exceeded forty-five (45) days, unless the alien can establish that due to emergent reasons, his or her return to the United States could not be accomplished within the time period allowed; (ii) the aggregate of all absence has not exceeded one hundred and eighty (180) days between January 1, 1982 through the date the application for temporary resident status is filed; (iii) the alien was maintaining residence in the United States; and (iv) the alien's departure from the United States was not based on an order of deportation. An alien who has been absent from the

United States in accordance with the Service's advance parole procedures shall not be considered as having interrupted his or her continuous residence as required at the time of filing an application.

(2) The term "continuous residence," as used in section 245A(b)(1)(B) of the Act, means that the alien shall be regarded as having resided continuously in the United States if, at the time of applying for adjustment from temporary residence to permanent resident status: No single absence from the United States has exceeded thirty (30) days, and the aggregate of all absences has not exceeded ninety (90) days between the date of granting of lawful temporary resident status and of applying for permanent resident status, unless the alien can establish that due to emergent reasons the return to the United States could not be accomplished within the time period(s) allowed.

(d) In the term "alien's unlawful status was known to the government," the term "government" means the Immigration and Naturalization Service. An alien's unlawful status was "known to the government" only if:

(1) The Service received factual information constituting a violation of the alien's nonimmigrant status from any agency, bureau or department, or subdivision thereof, of the Federal government, which information was stored or otherwise recorded in the official Service alien file, whether or not the Service took follow-up action on the information received. In order to meet the standard of "information constituting a violation of the alien's nonimmigrant status," the alien must have made a clear statement or declaration to the other federal agency, bureau or department that he or she was in violation of nonimmigrant status; or

(2) An affirmative determination was made by the Service prior to January 1, 1982 that the alien was subject to deportation proceedings. Evidence that may be presented by an alien to support an assertion that such a determination was made may include, but is not limited to, official Service documents issued prior to January 1, 1982, i.e., Forms I-94, Arrival-Departure Records granting a period of required departure; Forms I-210, Voluntary Departure Notice letter; Forms I-221, Order to Show Cause and Notice of Hearing, and Forms I-543, Order of Denial of Application for Change of Nonimmigrant Status granting a period of required departure. Evidence from Service records that may be used to support a finding that such a determination was made may include, but is not limited to, record copies of the aforementioned

forms and other documents contained in alien files, i.e., Forms I-213, Record of Deportable Alien; Unexecuted Forms I-205, Warrant of Deportation; Forms I-265, Application for Order to Show Cause and Processing Sheet; Forms I-541, Order of Denial of Application for Extension of Stay granting a period of required departure, or any other Service record reflecting that the alien's nonimmigrant status was considered by the Service to have terminated or the alien was otherwise determined to be subject to deportation proceedings prior to January 1, 1982, whether or not deportation proceedings were instituted.

(e) The term "to make a determination" as used in § 245a.2(t)(3) of this part means obtaining and reviewing all information required to adjudicate an application for the benefit sought and making a decision thereon. If fraud, willful misrepresentation of a material fact, providing of a false writing or document, or any other activity prohibited by section 245A(c)(6) of the Act is established during the process of making the determination on the application, the Service shall refer the United States Attorney for possible prosecution of the alien or of any person who created or supplied a false writing or document for use in an application for adjustment of status under this part. If prosecution is declined by the United States Attorney, the Service may issue an Order to Show Cause and Warrant of Arrest, unless the United States Attorney has notified the Service that the matter submitted is without merit.

(f) The term "physical presence" as used in section 245A(a)(3)(A) of the Act means actual continuous presence in the United States since date of enactment (11/6/86) until filing of any application for adjustment of status unless a departure is specifically authorized by the Service pursuant to the advance parole procedures set forth in § 212.5(e) of this chapter, or an alien unknowingly (without knowledge of such departure) departed the United States on or after November 6, 1986.

(g) The term "brief, casual, and innocent" means a departure authorized by the Service (advance parole) of not more than thirty (30) days for legitimate emergency or humanitarian purposes unless a further period of authorized departure has been granted in the discretion of the district director. Aliens who reenter or attempt to reenter the U.S. without inspection will not be considered as having made a brief, casual and innocent departure.

(h) The term "brief and casual" as used in section 245A(b)(3)(A) of the Act, means temporary trips abroad as long as

the alien establishes a continuing intention to adjust to lawful permanent resident status. However, such absences must not exceed the specific periods of time required in order to maintain continuous residence.

(j) The term "public cash assistance" means income or needs-based monetary assistance, to include but not limited to supplemental security income, received by the alien or his or her immediate family members through federal, state, or local programs designed to meet subsistence levels. It does not include assistance in kind, such as food stamps, public housing, or other non-cash benefits, nor does it include work-related compensation or certain types of medical assistance (Medicare, emergency treatment, services to pregnant women or children under 18 years of age, or treatment in the interest of public health).

(j) The term "Legalization Office" means local offices of the Immigration and Naturalization Service which accept and process applications for Legalization or Special Agricultural Worker status, under the authority of the INS district directors in whose districts such offices are located.

(k) The term "Regional Processing Facility" means Service offices established in each of the four Service regions to adjudicate, under the authority of the INS Directors of the Regional Processing Facilities, applications for adjustment of status under section 245A(a) or 245A(b)(1) of the Act.

(l) The term "designated entity" means any state, local, church, community, farm labor organization, voluntary organization, association of agricultural employers or individual determined by the Service to be qualified to assist aliens in the preparation of applications for Legalization status.

(m) The term "family unity" as used in section 245A(d)(2)(B)(i) of the Act means maintaining the family group without deviation or change. The family group shall include the spouse, unmarried minor children who are not members of some other household, and parents who reside regularly in the household of the family group.

(n) The term "prima facie" as used in section 245A(e)(1) and (2) of the Act means eligibility is established if the applicant presents a completed I-687 and specific factual information which in the absence of rebuttal proves a claim of eligibility under this part.

(o) The term "misdemeanor" means a crime punishable by imprisonment for a term of one year or less but more than

five days, regardless of the term such alien actually served, if any.

(p) The term "felony" means a crime, including a crime committed outside the United States, punishable by imprisonment for a term of more than one year regardless of the term such alien actually served, if any.

(q) The term "subject to an Order to Show Cause" means actual service of the Order to Show Cause upon the alien through the mail or by personal service.

§ 245a.2 Application for temporary residence.

(a) *Application period for temporary residence.* (1) An alien who has resided unlawfully in the United States since January 1, 1982, who believes that he or she meets the eligibility requirements of section 245A of the Act must make application within the twelve month period beginning on May 5, 1987 and ending on May 4, 1988.

(2)(i) An alien who was apprehended by the Service on or after November 6, 1986 and prior to May 5, 1987 and who has established prima facie eligibility for adjustment of status under section 245A(a) of the Act must file an application for adjustment during the period beginning on May 5, 1987 and ending on June 3, 1987.

(ii) An alien who is the subject of an Order to Show Cause issued under section 242 of the Act during the period beginning on May 5, 1987 and ending on April 4, 1988 must file an application for adjustment of status to that of a temporary resident prior to the thirty-first day after the issuance of the Order to Show Cause.

(iii) An alien who is the subject of an Order to Show Cause issued under section 242 of the Act during the period beginning on April 5, 1988 and ending on May 4, 1988 must file an application for adjustment of status to that of a temporary resident not later than May 4, 1988.

(iv) Failure of any alien described in paragraphs (a)(2)(i) through (iii) of this section to file an application for adjustment of status to that of a temporary resident under section 245A(a) of the Act during the respective time period(s) stipulated will render the alien statutorily ineligible for such adjustment of status.

(b) *Eligibility.* (1) The following categories of aliens who are otherwise admissible under section 212(a) of the Act are eligible to apply for status to that of a person admitted for temporary residence:

(i) An alien (other than an alien who entered as a nonimmigrant) who establishes that he or she entered the United States in an unlawful status prior

to January 1, 1982 and who has thereafter resided continuously in the United States and who has been physically present in the United States from November 6, 1986 until the date of filing the application.

(ii) An alien who establishes that he or she entered the United States as a nonimmigrant prior to January 1, 1982 and whose period of authorized admission expired through the passage of time prior to January 1, 1982 and who has thereafter resided continuously in the United States and who has been physically present in the United States from November 6, 1986 until the date of filing the application.

(iii) An alien who establishes that he or she entered the United States as a nonimmigrant prior to January 1, 1982 and whose unlawful status was known to the Government as of January 1, 1982 and who has thereafter resided continuously in the United States and who has been physically present in the United States from November 6, 1986 until the date of filing the application.

(iv) An alien described in paragraphs (b)(1)(i) through (iii) of this section was at any time a nonimmigrant exchange visitor (as defined in section 101(a)(15)(J) of the Act), must establish that he or she was not subject to the two-year foreign residence requirements of section 212(e) or has fulfilled that requirement or has received a waiver of such requirements and has resided continuously in the United States in unlawful status since January 1, 1982.

(v) An alien who establishes that he or she was granted voluntary departure, voluntary return, extended voluntary departure or placed in deferred action category by the Service prior to January 1, 1982 and who has thereafter resided continuously in the United States and who has been physically present in the United States from November 6, 1986 until the date of filing the application.

(vi) An alien who establishes that he or she was paroled into the United States prior to January 1, 1982, and whose parole status terminated prior to January 1, 1982 and who has thereafter resided continuously in the United States and who has been physically present in the United States from November 6, 1986 until the date of filing the application.

(vii) An alien who establishes that he or she is a national of Cuba or Haiti who entered the United States prior to January 1, 1982 and who has thereafter resided continuously in the United States and who has been physically present in the United States from November 6, 1986 until the date of filing the application, without regard to whether such alien

has applied for adjustment of status pursuant to section 202 of the Act.

(viii) An alien's eligibility under the categories described in §§ 245.2(a)(1)(i) through (vii) shall not be affected by entries to the United States subsequent to January 1, 1982 that were not documented on Service Form I-94, Arrival-Departure Record.

(c) *Ineligible aliens.* (1) An alien who has been convicted of a felony (including crimes committed outside of the United States), or three or more misdemeanors (committed in the United States).

(2) An alien who has assisted in the persecution of any person or persons on account of race, religion, nationality, membership in a particular social group or political opinion.

(3) An alien excludable under the provisions of section 212(a) of the Act whose grounds of excludability may not be waived, pursuant to section 245A(d)(2)(B)(ii) of this Act.

(4) An alien who at any time was a nonimmigrant exchange visitor who is subject to the two-year foreign residence requirement unless the requirement has been satisfied or waived pursuant to the provisions of section 212(e) of the Act who has resided continuously in the United States in an unlawful status since January 1, 1982.

(5) An alien who was in the custody of or apprehended by the Service on or after November 6, 1986 and prior to May 5, 1987 and has established prima facie eligibility for adjustment of status, who does not file an application for adjustment of status to that of a temporary resident under section 245A(a) of the Act, prior to June 4, 1987.

(6) An alien who is the subject of an Order to Show Cause issued under section 242 of the Act during the period beginning on May 5, 1987 and ending on April 4, 1988 who does not file an application for adjustment of status to that of temporary resident under section 245A(a) of the Act prior to the thirty-first day after issuance of the order.

(7) An alien who is the subject of an Order to Show Cause issued under section 242 of the Act during the period beginning on April 5, 1988 and ending on May 4, 1988 who does not file an application for adjustment of status to that of a temporary resident under section 245A(a) of the Act prior to May 5, 1988.

(8) An alien who was paroled into the United States prior to January 1, 1982 and whose parole status terminated subsequent to January 1, 1982.

(d) *Documentation.* Evidence to support an alien's eligibility for the legalization program shall include documents establishing proof of identity,

proof of residence, and proof of financial responsibility, as well as photographs, a completed fingerprint card (Form FD-258), and a completed medical report of examination (Form I-693). All documentation submitted will be subject to Service verification as to facts or authenticity. Applicants submitted with unverifiable documentation may be denied. Failure by an applicant to authorize release to INS of information protected by the Privacy Act and/or related laws in order for INS to adjudicate a claim may result in denial of the benefit sought. Acceptable supporting documents for these three categories are discussed below.

(1) *Proof of identity.* Evidence to establish identity is listed below in descending order of preference:

(i) Passport; (ii) Birth Certificate; (iii) Any national identity document from the alien's country of origin bearing photo and fingerprint (e.g., a "cedula" or "cartilla"); (iv) Driver's license or similar document issued by a state if it contains a photo; (v) Baptismal Record/Marriage Certificate; or (vi) Affidavits.

(A) *Assumed names.*

(1) *General.* In cases where an applicant claims to have met any of the eligibility criteria under an assumed name, the applicant has the burden of proving that the applicant was in fact the person who used that name. The applicant's true identity is established pursuant to the requirements of paragraph (d)(1) of this section. The assumed name must appear in the documentation provided by the applicant to establish eligibility. To meet the requirements of this paragraph documentation must be submitted to prove the common identity, i.e., that the assumed name was in fact used by the applicant.

(2) *Proof of common identity.* The most persuasive evidence is a document issued in the assumed name which identifies the applicant by photograph, fingerprint or detailed physical description. Other evidence which will be considered are affidavit(s) by a person or persons other than the applicant, made under oath, which identify the affiant by name and address, state the affiant's relationship to the applicant and the basis of the affiant's knowledge of the applicant's use of the assumed name. Affidavits accompanied by a photograph which has been identified by the affiant as the individual known to affiant under the assumed name in question will carry greater weight.

(2) *Proof of residence.* Evidence to establish proof of continuous residence in the United States during the requisite

period of time may consist of any combination of the following:

(i) Past employment records, which may consist of pay stubs, W-2 Forms, certified copies of income tax returns which were filed, letters from employer(s) or, if the applicant has been in business for himself or herself, letters from banks and other firms with whom he or she has done business. In all of the above, the name of the alien and the name of the employer or other interested organization must appear on the form or letter, as well as relevant dates. Letters from employers should be on employer letterhead stationary, if the employer has such stationary, and must include: (A) Alien's address at the time of employment; (B) exact period of employment; (C) periods of layoff; (D) duties with the company; (E) whether or not the information was taken from official company records; and (F) where records are located and whether the Service may have access to such records. If such records are unavailable, an affidavit form-letter stating that the alien's employment records are unavailable and why such records are unavailable may be accepted in lieu of paragraphs (d)(2)(i) (E) and (F) of this section stated in this paragraph. This affidavit form-letter shall be signed, attested to by the employer under penalty of perjury, and shall state the employer's willingness to come forward and give testimony if requested.

(ii) Utility bills (gas, electric, phone, etc.), receipts, or letters from companies showing the dates during which the applicant received service are acceptable documentation.

(iii) School records (letters, report cards, etc.) from the schools that the applicant or their children have attended in the United States must show name of school and periods of school attendance.

(iv) Hospital or medical records showing treatment or hospitalization of the applicant or his or her children must show the name of the medical facility or physician and the date(s) of the treatment or hospitalization.

(v) Attestations by churches, unions, or other organizations to the applicant's residence by letter which: (A) Identifies applicant by name; (B) is signed by an official (whose title is shown); (C) shows inclusive dates of membership; (D) states the address where applicant resided during membership period; (E) includes the seal of the organization impressed on the letter or the letterhead of the organization, if the organization has letterhead stationary; (F) establishes how the author knows the applicant;

and (G) establishes the origin of the information being attested to.

(vi) Additional documents to support the applicant's claim may include:

- (A) Money order receipts for money sent in or out of the country;
- (B) Passport entries;
- (C) Birth certificates of children born in the United States;
- (D) Bank books with dated transactions;
- (E) Letters or correspondence between applicant and another person or organization;

(F) Social Security card;

(G) Selective Service card;

(H) Automobile license receipts, title, vehicle registration, etc.;

(I) Deeds, mortgages, contracts to which applicant has been a party;

(J) Tax receipts;

(K) Insurance policies, receipts, or letters; and

(L) Any other relevant document.

(3) *Proof of financial responsibility.*

An applicant for adjustment of status under this part is subject to the provisions of section 212(a)(15) of the Act relating to excludability of aliens likely to become public charges unless the applicant demonstrates a history of employment in the United States evidencing self-support without receipt of public cash assistance. Generally, the evidence of employment submitted under paragraph (d)(2)(i) of this section will serve to demonstrate the alien's financial responsibility during the document period(s) of employment. If the alien's period(s) of residence in the United States include significant gaps in employment or if there is reason to believe that the alien may have received public assistance while employed, the alien may be required to provide proof that he or she has not received public cash assistance. An applicant for residence who is likely to become a public charge will be denied adjustment. The burden of proof to demonstrate the inapplicability of this provision of law lies with the applicant who may provide:

(i) Evidence of a history of employment (i.e., employment letter, W-2 Forms, income tax returns, etc.);

(ii) Evidence that he/she is self-supporting (i.e., bank statements, stocks, other assets, etc.); or

(iii) Form I-134, Affidavit of Support, completed by a spouse in behalf of the applicant and/or children which guarantees complete or partial financial support of the applicant.

(4) *Burden of proof.* An alien applying for adjustment of status under this part has the burden of proving by a preponderance of the evidence that he or she resided in the United States for the requisite periods, is admissible to

the United States under the provisions of section 245a of the Act, and is otherwise eligible for adjustment of status under this section. The inference to be drawn from the documentation provided shall depend on the extent of the documentation, its credibility and amenability to verification as set forth in paragraph (d) of this section.

(5) *Evidence.* The sufficiency of all evidence produced by the applicant will be judged according to its probative value and credibility. To meet his or her burden of proof, an applicant must provide evidence of eligibility apart from his or her own testimony. In judging the probative value and credibility of the evidence submitted greater weight will be given to the submission or original documentation.

(e) *Filing of application:* (1) The application must be filed on Form I-687 at an office of a designated entity or at a Service Legalization Office within the jurisdiction of the District wherein the applicant resides. If the application is filed with a designated entity, the alien must have consented to having the designated entity forward the application to the legalization office. In the case of applications filed at a legalization office, the district director may, at his or her discretion: (i) Require the applicant to file the application in person; or (ii) require the applicant to file the application by mail; or (iii) permit the filing of applications either by mail or in person. The applicant must appear for a personal interview at the legalization office when scheduled. If the applicant is 14 years of age or older, the application must be accompanied by a completed Form FD-258 (Applicant Card).

(2) Wherever possible documents must be submitted in the original except the following: Official government records; employment or employment-related records maintained by employers, unions, or collective bargaining organizations; school records maintained by a school or school board; or other records maintained by a party other than the applicant. Copies of records maintained by parties other than the applicant which are submitted in evidence must be certified as true and correct by such parties and must bear their seal or signature or the signature and title of persons authorized to act in their behalf. If the return of original documents is desired by the applicant, they must be accompanied by notarized copies or copies certified true and correct by a designated entity or by the alien's representative in the format prescribed in § 204.2(j)(1) or (2) of this chapter. Such certified copies unaccompanied by original documents

are unacceptable for the purpose of an application under this part. At the discretion of the district director, original documents, even if accompanied by certified copies, may be temporarily retained for forensic examination by the Document Analysis Unit at the Regional Processing Facility having jurisdiction over the legalization office to which the documents were submitted.

(3) A separate application (I-687) must be filed by each eligible applicant. All fees required by § 103.7(b)(1) of this chapter must be submitted in the exact amount in the form of a money order, cashier's check, or certified bank check, made payable to the Immigration and Naturalization Service. No personal checks or cash will be accepted. Fees will not be waived or refunded under any circumstances.

(f) *Filing date of application.* The date the alien submits a completed application to a Service Legalization Office or designated entity shall be considered the filing date of the application, provided that the case of an application filed at a designated entity the alien has consented to having the designated entity forward the application to the Service Legalization Office having jurisdiction over the location of the alien's residence. The designated entities are required to forward completed applications to the appropriate Service Legalization Office within sixty days of receipt.

(g) *Selective Service Registration:* At the time of filing an application under this section, male applicants between the ages of 18 and 26 are required to be registered under the Military Selective Service Act. An applicant shall present evidence that he has previously registered under that Act, in the form of a letter of acknowledgement from the Selective Service System, or such alien shall present a completed and signed Form SSS-1 at the time of filing Form I-687 with the Immigration and Naturalization Service or a designated entity. Form SSS-1 will be forwarded to the Selective Service System by the Service.

(h) *Continuous residence.* (1) For the purpose of this Act, an applicant for temporary resident status shall be regarded as having resided continuously in the United States if, at the time of filing of the application: (i) No single absence from the United States has exceeded forty-five (45) days, unless the alien can establish that due to emergent reasons, his or her return to the United States could not be accomplished within the time period allowed; (ii) the aggregate of all absences has not

exceeded one hundred and eighty (180) days between January 1, 1982 through the date the application for temporary resident status is filed; (iii) the alien was maintaining a residence in the United States; and (iv) the alien's departure from the United States was not based on an order of deportation.

(2) An alien who has been absent from the United States in accordance with the Service's advance parole procedures shall not be considered as having interrupted his or her continuous residence as required at the time of filing an application under this section.

(i) *Medical examination.* An applicant under this part shall be required to submit to an examination by a selected civil surgeon. The selected civil surgeon shall report the findings of the mental and physical condition of the applicant and the determination of the alien's immunization status. Results of the medical examination must be presented to the Service at the time of interview and shall be incorporated into the record. Any applicant certified under paragraphs (1), (2), (3), (4), or (5) of section 212(a) of the Act may appeal to a Board of Medical Officers of the U.S. Public Health Service as provided in section 234 of the Act and Part 235 of this chapter.

(j) *Interview.* Each applicant, regardless of age, must appear at the appropriate Service Legalization Office and must be fingerprinted for the purpose of issuance of Form I-688. Each applicant shall be interviewed by an immigration officer, except that the interview may be waived for a child under 14, or when it is impractical because of the health or advanced age of the applicant.

(k)(1) *Grounds of exclusion not to be applied.* The following paragraphs of section 212(a) of the Act shall not apply to applicants for temporary resident status: (14) Workers entering without Labor Certification; (20) immigrants not in possession of valid entry documents; (21) visas issued without compliance with section 203; (25) illiterates; and (32) graduates of non-accredited medical schools.

(2) *Waiver of grounds of exclusion.* Except as provided in paragraph (k)(3) of this section, the Attorney General may waive any other provision of section 212(a) of the Act only in the case of individual aliens for humanitarian purposes, to assure family unity, or when the granting of such a waiver is in the public interest. If an alien is excludable on grounds which may be waived as set forth in this paragraph, he or she shall be advised of the procedures for applying for a waiver of grounds of excludability on Form I-690.

When an application for waiver of grounds of excludability is filed jointly with an application for temporary residence under this section, it shall be accepted for processing at the legalization office. If an application for waiver of grounds of excludability is submitted after the alien's preliminary interview at the legalization office, it shall be forwarded to the appropriate Regional Processing Facility. All applications for waivers of grounds of excludability must be accompanied by the correct fee in the exact amount. All fees for applications filed in the United States must be in the form of a money order, cashier's check, or bank check. No personal checks or cash will be accepted. Fees will not be waived or refunded under any circumstances. An application for waiver of grounds of excludability under this part shall be approved or denied by the director of the Regional Processing Facility in whose jurisdiction the applicant's application for adjustment of status was filed, except that in cases involving clear statutory ineligibility or admitted fraud, such application may be denied by the district director in whose jurisdiction the application is filed, and in cases returned to a Service Legalization Office for re-interview, such application may be approved at the discretion of the district director. The applicant shall be notified of the decision and, if the application is denied, of the reason therefor. A party affected under this part by an adverse decision may appeal the decision within 30 days after the service of the notice only to the Service's Administrative Appeals Unit pursuant to the provisions of § 103.3(a) of this chapter.

(3) *Grounds of exclusion that may not be waived.* Notwithstanding any other provision of the Act, the following provisions of section 212(a) may not be waived by the Attorney General under paragraph (k)(2) of this section: (i) Paragraphs (9) and (10) (criminals); (ii) Paragraph (15) (public charge); (iii) Paragraph (23) (narcotics) except for a single offense of simple possession of thirty grams or less of marijuana; (iv) Paragraphs (27) (prejudicial to the public interest), (28) (communist), and (29) (subversive); (v) Paragraph (33) (Nazi persecution).

(4) *Special rule for determination of public charge.* An alien who has a consistent employment history which shows the ability to support himself and his or her family even though his income may be below the poverty level is not excludable under paragraph (k)(3)(ii) of this section. The alien's employment history need not be continuous in that it is uninterrupted. It should be continuous

in the sense that the alien shall be regularly attached to the workforce, has an income over a substantial period of the applicable time, and has demonstrated the capacity to exist on his or her income and maintain his or her family without recourse to public cash assistance. This regulation is prospective in that the Service shall determine, based on the alien's history, whether he or she is likely to become a public charge. Past acceptance of public cash assistance within a history of consistent employment will enter into this decision. The weight given in considering applicability of the public charge provisions will depend on many factors, but the length of time an applicant has received public cash assistance will constitute a significant factor.

(5) *Public Assistance and Criminal History Verification.* Declarations by an applicant that he or she has not been the recipient of public cash assistance and/or has not had a criminal record are subject to a verification of facts by the Service. The applicant must agree to fully cooperate in the verification process. Failure to assist the Service in verifying information necessary for proper adjudication may result in a denial of the application.

(l) *Continuous physical presence since November 6, 1986.* (1) An alien applying for adjustment to temporary resident status must establish that he or she has been continuously physically present in the United States since November 6, 1986.

(2) Brief, casual and innocent absences from the United States shall not be considered to interrupt the continuous physical presence required in paragraph (l)(1) of this section. A brief, casual and innocent absence is defined as a departure authorized by the Service of not more than thirty (30) days for legitimate emergency or humanitarian purposes unless a further period of authorized departure has been granted at the discretion of the district director.

(m) *Departure.* (1) During the time period from the date that an alien's application establishing prima facie eligibility for temporary resident status is reviewed at a Service Legalization Office and the date status as a temporary resident is granted, the alien applicant can only be readmitted to the United States provided his or her departure was authorized under the Service's advance parole provisions contained in § 212.5(e) of this chapter.

(2) An alien whose application for temporary resident status has been approved may be admitted to the United

States upon return as a returning temporary resident provided he or she:

(i) Is not under deportation proceedings;

(ii) Has not been absent from the United States more than thirty (30) days on the date application for admission is made;

(iii) Has not been absent from the United States for an aggregate period of more than 90 days since the date the alien was granted lawful temporary resident status;

(iv) Presents Form I-688; and

(v) Presents himself or herself for inspection.

(3) the period of time in paragraph (m)(2)(ii) of this section may be waived at the discretion of the Attorney General in cases where the absence from the United States was due merely to a brief temporary trip abroad required due to emergent or extenuating circumstances beyond the alien's control.

(n)(1) *Employment and travel authorization; general.* Authorization for employment and travel abroad for temporary resident status applicants under section 245A(a) of the Act may only be granted by a Service Legalization Office. In the case an application which has been filed with a designated entity, employment authorization may only be granted by the Service after the application has been properly received at the Service Legalization Office.

(2) *Employment authorization prior to the granting of temporary resident status.* Permission to accept employment will be granted to the applicant upon review of an application establishing prima facie eligibility for temporary resident status. Applications may be presented in person, through designated entities, or through the mail to a legalization office. Applicants who walk-in or mail-in their applications to offices that schedule appointments will receive a form letter fee receipt and scheduled appointment. If an appointment cannot be scheduled within thirty (30) days, authorization to accept employment will be given valid to the scheduled appointment date. Form I-688A, Employment Authorization, will be given to the applicant after an interview has been completed by an immigration officer. This temporary employment authorization will be restricted to six months duration, pending final determination on the application for temporary resident status.

(3) *Employment and travel authorization upon grant of temporary resident status.* Upon grant of an application for adjustment to temporary resident status by a Regional Processing

facility, the processing facility will forward a notice of approval to the alien at his or her last known address and to his or her designated entity or representative. The alien will be required to return to the Service Legalization Office where the application was initially received, surrender the I-688A previously issued, and will be issued Form I-688, Temporary Resident Card, authorizing employment and travel abroad.

(4) *Revocation of employment authorization upon denial of temporary resident status.* Upon denial of an application for adjustment to temporary resident status by a Regional Processing Facility, Notice of Revocation of employment authorization will be forwarded to the alien at his or her last known address. Employment authorization will not be granted solely on the basis of an appeal having been filed.

(o) *Decision.* The applicant shall be notified in writing of the decision, and, if the application is denied, of the reason therefor. A party affected under this part by an adverse decision is entitled to file an appeal on Form I-694.

(p) *Appeal process.* An adverse decision under this part may be appealed to the Associate Commissioner, Examinations (Administrative Appeals Unit). Any appeal with the required fee shall be filed with the Regional Processing Facility within thirty (30) days after service of the notice of denial in accordance with the procedures of section 103.3(a) of this chapter. An appeal received after the thirty (30) day period has tolled will not be accepted. The thirty (30) day period includes any time required for service or receipt by mail.

(q) *Motions.* The Regional Processing Facility director may *sua sponte* reopen and reconsider any adverse decision. When an appeal to the Associate Commissioner, Examinations (Administrative Appeals Unit) has been filed, and the INS director of the Regional Processing Facility may issue a new decision that will grant the benefit which has been requested. The director's new decision must be served on the appealing party within 45 days of receipt of any briefs and/or new evidence, or upon expiration of the time allowed for the submission of any briefs.

(r) *Certifications.* The Regional Processing Facility director may, in accordance with § 103.4 of this chapter, certify a decision to the Associate Commissioner, Examinations (Administrative Appeals Unit) when the case involves an unusually complex or novel question of law or fact.

(s) *Date of adjustment to temporary residence.* The status of an alien whose application for temporary resident status is approved shall be adjusted to that of a lawful temporary resident as of the date on which the application was fee received at a Service Legalization Office.

(t) *Limitation on access to information and confidentiality.* (1) No person other than a sworn officer or employee of the Justice Department or bureau or agency thereof, will be permitted to examine individual applications, except employees of designated entities where applications are filed with the same designated entity. For purposes of this part, any contract personnel employed by the Service to work in connection with the legalization program shall be considered an "employee of the Justice Department or bureau or agency thereof."

(2) Files and records prepared by designated entities under this section are confidential. The Attorney General and the Service shall not have access to these files and records without the consent of the alien.

(3) No information furnished pursuant to an application for legalization under this section shall be used for any purpose except: (i) To make a determination on the application; or, (ii) for the enforcement of the provisions encompassed in section 245A(c)(6) of the Act, except as provided in paragraph (t)(4) of this section.

(4) If a determination is made by the Service that the alien has, in connection with his or her application, engaged in fraud or willful misrepresentation of a material fact, provided a false writing or document in making his or her application, or engaged in any other activity prohibited by section 245A(c)(6) of the Act, the Service shall refer the matter to the United States Attorney for possible prosecution of the alien or of any person who created or supplied a false writing or document for use in an application for adjustment of status under this part. If prosecution is declined by the United States Attorney, the Service may issue an order to show cause and warrant of arrest, unless the United States Attorney has notified the Service that the matter submitted is without merit.

(5) If the investigation conducted by the Service results in the conviction of an applicant for a violation of section 245A(c)(6) of the Act, the applicant shall be considered to be inadmissible to the United States on the ground described in section 212(a)(19) of the Act.

(6) Information obtained in a granted legalization application and contained

in the applicant's file in subject to subsequent review in reference to future benefits applied for (including petitions for naturalization and permanent resident status for relatives).

(u) *Termination of temporary resident status.* (1) Termination of temporary resident status; General. The status of an alien lawfully admitted for temporary residence under section 245A(a)(1) of the Act may be terminated at any time in accordance with section 245A(b)(2) of the Act. It is not necessary that a final order of deportation be entered in order to terminate temporary resident status. The temporary resident status may be terminated upon the occurrence of any of the following:

(i) It is determined that the alien was ineligible for temporary residence under 245A of this Act;

(ii) The alien commits an act which renders him or her inadmissible as an immigrant, except as provided under § 245a.2(k) (2) or (3) of this part;

(iii) The alien is convicted of any felony (including crimes committed outside of the United States), or three or more misdemeanors (committed in the United States);

(iv) The alien fails to file for adjustment of status from temporary resident to permanent resident on Form I-698 within thirty-one (31) months of the date he/she was granted status as a temporary resident under § 245a.1 of this part.

(2) *Procedure.* Termination of an alien's status under paragraph (u)(1) of this section will be made only on notice to the alien sent by certified mail directed to his or her last known address. The alien must be given an opportunity to offer evidence in opposition to the grounds alleged for termination of his or her status. Evidence in opposition must be submitted within thirty (30) days after the service of the Notice of Intent to Terminate. If the alien's status is terminated, the director of the regional processing facility shall notify the alien of the decision and the reasons for the termination, and further notify the alien that any Service Form I-94, Arrival-Departure Record or other official Service document issued to the alien authorizing employment and/or travel abroad, or any Form I-688, Temporary Resident Card previously issued to the alien will be declared void by the director of the regional processing facility within thirty (30) days if no appeal of the termination decision is filed within that period. The alien may appeal the decision to the Associate Commissioner, Examinations (Administrative Appeals Unit). Any appeal with the required fee shall be

filed with the regional processing facility within thirty (30) days after the service of the notice of termination. If no appeal is filed within that period, the I-94, I-688 or other official Service document shall be deemed void, and must be surrendered without delay to an immigration officer or to the issuing office of the Service.

(3) *Termination not construed as rescission under section 246.* For the purposes of this part the phrase "termination of status" of an alien granted lawful temporary residence under section 245A(a) of the Act shall not be construed to necessitate a rescission of status as described in section 246 of the Act, and the proceedings required by the regulations issued thereunder shall not apply.

(4) *Return to unlawful status after termination.* Termination of the status of any alien previously adjusted to lawful temporary residence under section 245A(a) of the Act shall act to return such alien to the unlawful status held prior to the adjustment, and render him or her amendable to exclusion or deportation proceedings under section 236 or 242 of the Act, as appropriate.

§ 245a.3 Application for adjustment of status from temporary to permanent resident

(a) *Application period for permanent residence.* An alien who has resided in the United States for a period of eighteen (18) months after the granting of temporary resident status may make application for permanent resident status during the twelve month period beginning on the day after the requisite eighteen months temporary residence has been completed. Applications for lawful permanent residence under section 245A(b)(1) of the Act will be accepted at legalization offices beginning on November 7, 1988.

(b) *Eligibility.* Any alien physically present in the United States who has been lawfully admitted for temporary resident status under section 245A(a) of the Act, may apply for adjustment of status to that of an alien lawfully admitted for permanent residence if the alien:

(i) Applies for such adjustment during the one-year period beginning with the nineteenth month that begins after the date the alien was granted such temporary resident status;

(2) Establishes continuous residence in the United States since the date the alien was granted such temporary residence status. An alien shall be regarded as having resided continuously in the United States for the purposes of this part if, at the time of applying for adjustment from temporary to

permanent resident status, no single absence from the United States has exceeded thirty (30) days, or the aggregate of all absences has not exceeded ninety (90) days between the date of granting of lawful temporary resident status and applying for permanent resident status unless the alien can establish that due to emergent reasons, the return to the United States could not be accomplished within the time period(s) allowed.

(3) Is admissible to the United States as an immigrant, except as otherwise provided in paragraph (f) of this section; and has not been convicted of any felony (including crimes committed outside of the United States), or three or more misdemeanors committed in the United States); and

(4)(i)(A) can demonstrate that the alien either; (1) Meets the requirements of section 312 of the Immigration and Nationality Act, as amended, (relating to minimal understanding of ordinary English and a knowledge and understanding of the history and government of the United States), or; (2) is satisfactorily pursuing a course of study recognized by the Attorney General to achieve such an understanding of English and such a knowledge and understanding of the history and government of the United States, or; (B) has demonstrated that the alien met the requirements of paragraph (b)(4)(i)(A)(1) of this section at the time of interview for adjustment of status to that of lawful temporary resident under section 245A(a); or (C) the requirements of paragraph (b)(4)(i)(A)(1) of this section may be waived at the discretion of the Attorney General if the alien is 65 years or older.

(ii) A course of study in the English language and in the history and government of the United States shall satisfy the requirement or paragraph (b)(4)(i)(A)(2) of this section; if (A) It is sponsored or conducted by an established public or private institution of learning recognized as such by a qualified state certifying agency, or by an institution of learning approved to issue Forms I-20 in accordance with § 214.3 of this chapter, or by a qualified designated entity within the meaning of section 245A(c)(2) of the Act; and (B) the course materials for such instruction include textbooks published under the authority of section 346 of the Act.

(c) *Ineligible aliens.* (1) An alien who has been convicted of a felony (including crimes committed outside of the United States), or three or more misdemeanors (committed in the United States).

(2) An alien who has assisted in the persecution of any person or persons on account of race, religion, nationality, membership in a particular social group or political opinion.

(3) An alien excludable under the provisions of section 212(e) of the Act whose grounds of excludability may not be waived, pursuant to section 245(d)(2)(B)(ii) of the Act.

(4) An alien who was previously granted temporary resident status pursuant to section 245A(a) of the Act who has not filed an application for permanent resident status under section 245A(b)(1) of the Act during the one year period which began with the nineteenth month that begins after the date the alien was granted such temporary resident status.

(5) An alien who was not previously granted temporary resident status under section 245A(a) of the Act.

(d) *Filing of application.* (1) The application must be filed on Form I-698 in person at a designated Legalization Office within the jurisdiction of the District wherein the applicant resides. Form I-698 must be accompanied by the documents specified in the instructions. If the alien is 14 years or older, the application must be accompanied by a completed Form FD-258 (Fingerprint Card).

(2) All documents must be submitted in the original except the following: Official government records; employment or employment-related records maintained by employers, unions, or collective bargaining organizations; school records maintained by a school or school board; or other records maintained by a party other than the applicant. Copies of records maintained by parties other than the applicant which are submitted in evidence must be certified as true and correct by such parties and must bear their seal or signature or the signature and title of persons authorized to act in their behalf. If the return of original documents is desired by the applicant, they must be accompanied by notarized copies or copies certified true and correct by a designated entity or by the alien's representative in the format prescribed in § 204.2(j) (1) or (2) of this chapter. Such certified copies unaccompanied by original documents are unacceptable for the purpose of an application under this part. At the discretion of the district director, original documents, even if accompanied by certified copies, may be temporarily retained for forensic examination by the Document Analysis Unit at the Regional Processing Facility having jurisdiction over the legalization

office to which the documents were submitted.

(3) A separate application (I-698) must be filed by each eligible applicant. All fees required by § 103.7(b)(1) of this chapter must be submitted in the exact amount in the form of a money order, cashier's check or certified bank check. No personal checks or currency will be accepted. Fees will not be waived or refunded under any circumstances.

(e) *Interview.* Each applicant, regardless of age, must appear at the appropriate Service legalization office and must be fingerprinted for the purpose of issuance of Form I-551. Each applicant shall be interviewed by an immigration officer, except that the interview may be waived for a child under 14, or when it is impractical because of the health or advanced age of the applicant.

(f) *Numerical limitations.* The numerical limitations of sections 201 and 202 of the Act do not apply to the adjustment of aliens to lawful permanent resident status under section 245A(b) of the Act.

(g) (1) *Grounds of exclusion not to be applied.* The following paragraphs of section 212(a) of the Act shall not apply to applicants for adjustment of status from temporary resident to permanent resident status; (14) workers entering without Labor Certification; (20) immigrants not in possession of valid entry document; (21) visas issued without compliance of section 203; (25) illiterates; and (32) graduates of non-accredited medical schools.

(2) *Waiver of grounds of excludability.* Except as provided in paragraph (g)(4) of this section, the Service may waive any provision of section 212(a) of the Act only in the case of individual aliens for humanitarian purposes, to assure family unity, or when the granting of such a waiver is otherwise in the public interest. In any case where a provision of section 212(a) of the Act has been waived in connection with an alien's application for lawful temporary resident status under section 245A(a) of the Act, no additional waiver of the same ground of excludability will be required when the alien applies for permanent resident status under 245A(b)(1) of the Act. In the event that the alien becomes excludable under any other provision of section 212(a) of the Act subsequent to the date temporary residence was granted, a waiver of the additional ground of excludability will be required before permanent resident status may be granted.

(3) *Grounds of exclusion that may not be waived.* Notwithstanding any other provision of the Act the following

provisions of section 212(a) of the Act may not be waived by the Attorney General under paragraph (g)(2) of this section:

(i) Paragraphs (9) and (10) (criminals);

(ii) Paragraph (15) (public charge) insofar as it relates to an application for adjustment to permanent residence by an alien other than an alien who is eligible for benefits under Title XVI of the Social Security Act or section 212 of Pub. L. 93-66 for the month in which such alien is granted lawful temporary residence status under subsection (a);

(iii) Paragraph (23) (narcotics), except for a single offense of simple possession of thirty grams or less of marijuana;

(iv) Paragraphs (27) (prejudicial to the public interest), (28) (communists), and (29) (subversive);

(v) Paragraph (33) (Nazi persecution).

(4) *Special rule for determination of public charge.* An alien who has a consistent employment history which shows the ability to support himself or herself and his or her family even though his or her income may be below the poverty level is not excludable under paragraph (g)(3)(ii) of this section. The alien's employment history need not be continuous in that it is uninterrupted. It should be continuous in the sense that the alien shall be regularly attached to the workforce, has an income over a substantial period of the applicable time, and has demonstrated the capacity to exist on his or her income and maintain his or her family without recourse to public cash assistance. This regulation is prospective in that the Service shall determine, based on the alien's history, whether he or she is likely to become a public charge. Past acceptance of public cash assistance within a history of consistent employment will enter into this decision. The weight given in considering applicability of the public charge provisions will depend on many factors, but the length of time an applicant has received public cash assistance will constitute a significant factor.

(5) *Public cash assistance and criminal history verification.*

Declarations by an applicant that he or she has not been the recipient of public cash assistance and/or has not had a criminal record are subject to a verification of facts by the Service. The applicant must agree to fully cooperate in the verification process. Failure to assist the Service in verifying information necessary for proper adjudication may result in a denial of the application.

(h) *Departure.* An applicant for adjustment to lawful permanent resident status under section 245A(b)(1) of the

Act who was granted lawful temporary resident status under section 245A(a) of the Act, shall be permitted to return to the United States after such brief and casual trips abroad, as long as the alien reflects a continuing intention to adjust to lawful permanent resident status. However, such absences from the United States must not exceed the periods of time specified in § 245a.3(b)(2) of this chapter in order for the alien to maintain continuous residence as specified in the Act.

(i) *Decision.* The applicant shall be notified in writing of the decision, and, if the application is denied, of the reason therefor. A party affected under this part by an adverse decision is entitled to file an appeal on Form I-694.

(j) *Appeal Process.* An adverse decision under this part may be appealed to the Associate Commissioner, Examinations (Administrative Appeals Unit). Any appeal with the required fee shall be filed with the Regional Processing Facility within thirty (30) days after service of the Notice of Denial in accordance with the procedures of § 103.3(a) of this chapter. An appeal received after the thirty (30) day period has tolled will not be accepted. The thirty (30) day period includes any time required for service or receipt by mail.

(k) *Motions.* The Regional Processing Facility director may *sua sponte* reopen and reconsider any adverse decision. When an appeal to the Associate Commissioner, Examinations (Administrative Appeals Unit) has been filed, the INS director of the Regional Processing Facility may issue a new decision that will grant the benefit which has been requested. The director's new decision must be served on the appealing party within forty-five (45) days of receipt of any briefs and/or new evidence, or upon expiration of the time allowed for the submission of any briefs.

(l) *Certifications.* The regional processing facility director may, in accordance with § 103.4 of this chapter, certify a decision to the Associate Commissioner, Examinations (Administrative Appeals Unit) when the case involves an unusually complex or novel question of law or fact.

(m) *Date of Adjustment to Permanent Residence.* The status of an alien whose application for permanent resident status is approved shall be adjusted to that of a lawful permanent resident as of the date on which the application is approved by the director of the regional processing facility.

Dated: March 5, 1987.

Alan C. Nelson,

Commissioner.

[FR Doc. 87-5838 Filed 3-7-87; 10:07 am]

BILLING CODE 4410-10-M

8 CFR Parts 109 and 274a

Control of Employment of Aliens

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Proposal rule.

SUMMARY: The proposed changes would add Part 274a and redesignate Part 109 with minor changes as Subpart B, by: (1) The addition of definitions to clarify the regulations; (2) addition of new sections to establish procedures for the verification of employment eligibility for workers in the United States; (3) addition of new sections to establish enforcement and process procedures for violations; (4) redesignating Part 109 (Employment Authorization) as Subpart B of Part 274a to consolidate what would otherwise be dispersed regulations under one part for clarity and uniformity. These additions are necessitated by the provisions of the recently passed Immigration Reform and Control Act of 1986, Pub. L. 99-603, which amended the Immigration and Nationality Act (Act) by adding provisions relating to the control of illegal immigration. These provisions make it unlawful to hire, recruit or refer for a fee, unauthorized aliens for employment in the United States. The statute also requires the establishment of an employment eligibility verification system designed to prevent the employment of unauthorized aliens. Prompt establishment of the procedures contained in these proposed regulations is necessary in order to ensure that Service operations are conducted in a manner consistent with the public interest and Congressional intent of the Act. For these reasons, this rule is proposed for solicitation of comments, which will be considered in formulating the final regulations.

DATE: Comments must be submitted on or before April 20, 1987.

ADDRESS: Please submit written comments in triplicate to: Office of Investigations, Immigration and Naturalization Service, 425 I Street, NW., Room 7240, Washington, DC 20536.

FOR FURTHER INFORMATION CONTACT:

Walter D. Cadman, Senior Special Agent, Immigration and Naturalization Service, 425 I Street, NW., Washington, DC 20536. Telephone: (202) 633-2997.

SUPPLEMENTARY INFORMATION:

Background

Since 1972 numerous attempts have been made by Congress and recent Administrations to pass immigration reform legislation. The imposition of sanctions on employers has been a cornerstone of nearly all such attempts with the view that curbing illegal immigration would not be effective without such sanctions. The Select Commission on Immigration and Refugee Policy was established by Congress in October 1978. It was created to review immigration policy issues, assess the impact of legal and illegal immigrants on the nation, and recommend changes in policy and practice. The Commission made a series of over seventy recommendations concerning these issues in its final report in May 1981. Those recommendations included the imposition of employer sanctions to control illegal immigration. Thereafter a Cabinet level task force reviewed the Select Commission Report and other recommendations on immigration reform. In 1981 and 1982 alone some twenty-eight hearings were conducted by House and Senate immigration subcommittees on proposed immigration reform.

On November 6, 1986, after fourteen years of immigration reform legislation history the President signed into law the Immigration Reform and Control Act of 1986, Pub. L. 99-603, (IRCA). This legislation is the most comprehensive reform of our immigration laws in thirty-five years. The employer sanctions provisions of IRCA are one of three cornerstone on which immigration reform is based. The other two are increased enforcement measures and legalization. Legalization is being addressed separately from these proposed rules.

Statutory authority

Section 101 of IRCA is designed to control the unlawful employment of aliens in the United States by imposing civil and criminal penalties on those persons and entities that hire, recruit or refer for a fee unauthorized aliens. Section 101 of IRCA amends the Act by adding section 274A which closes a large gap in the enforcement of our immigration laws by: (1) Making it unlawful to hire, recruit or refer for a fee unauthorized aliens; (2) requiring those who hire, recruit or refer for a fee individuals for employment, to verify both the identity and employment eligibility of such individuals and (3) making it unlawful to continue to employ unauthorized aliens hired after

November 6, 1986. While section 112 of the IRCA amends section 274(a) of the Act (which sets forth criminal penalties for individuals who harbor illegal aliens), employment of illegal aliens in and of itself does not constitute harboring under section 274(a) of the Act as amended.

While the changes to Part 109 are minor, INS recognizes that further changes are necessary and invites comments on this part.

Drafting Information and Enforcement Strategy

Since 1975 INS has vigorously worked in the spirit of cooperation with employers on an ad hoc basis to encourage a policy of employing only U.S. citizens and aliens lawfully authorized to work in the United States. The success of this effort, called Operation Cooperation, has been encouraging, but with the limits of INS resources and lack of statutory backing such programs have been of limited effectiveness. Mandatory compliance is the only effective mechanism that reduces "pull" factors that encourage rather than discourage illegal immigration.

Since enactment of IRCA on November 6, 1986, INS has been working to develop these rules along with a balanced enforcement policy. On January 20, 1987, INS took the unprecedented step of publishing a notice in the *Federal Register* to solicit comments from the public and other interested parties concerning draft rules implementing the employer provisions of IRCA. Interested parties were provided with preliminary working drafts for review and comments. Comments were received from over 100 individuals or groups, including Congressional sources, law firms, interest groups, business and labor organizations, and educational institutions. These comments were reviewed and elevated in the development of this proposed rule. Many of the comments and suggestions were incorporated in this text including but not limited to: simplification of Employment Eligibility Verification (Form I-9); restructuring the text to minimize the amount of information required to be referenced by those affected; simplification and clarification of the text language; and clarification of several provisions to minimize the impact on those affected, such as the compliance period and rehire issues. The proposed rule specifies that the point at which the employment eligibility verification must take place is at the time of hire or referral to an employer. The Service invites comment on issues concerning the nature of

verification, the mandatory and universal aspect of the requirements for employers to complete and maintain the designated form, and the application of penalties to procedural as well as substantive violations of the Act.

While this proposed rule will not satisfy the concerns of all those who commented, INS feels that most issues have been addressed in the spirit of mutual dialogue with the intent of minimizing the impact of this far reaching legislation on the affected parties, to the extent permitted by the statute, Congressional intent and the public interest.

INS will continue to encourage voluntary cooperation and compliance along with traditional enforcement in achieving the goal of this legislation. In an effort to achieve this objective, INS has established a new office for Employer and Labor Relations at the assistant commissioner level to administer a staff dedicated to education and cooperation with the employers and other interested parties. Many public appearances have been made by INS officials in the last few months to inform and solicit comments from interested parties. INS envisions a balanced approach between education/cooperation and strict enforcement of penalties for egregious violators. INS intends to continue a process of dialogue during the comment period.

Other Information

A statement concerning the proposed Employment Eligibility Verification, Form I-9, is being submitted concurrently with this notice, to OMB for review in accordance with the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

This proposed rule is a major rule within the context of E.O. 12291 in terms of the effect it will have on the national economy. A Preliminary Regulatory Impact Analysis in conjunction with a Regulatory Flexibility Analysis as required by 5 U.S.C. 603 and 604, is being prepared, and will be available for review by the public upon request.

List of Subjects in 8 CFR Parts 109, 274a

Administrative practice and procedure, aliens, employment.

For the reasons set out in the preamble, INS proposes to amend Chapter I of Title 8 of the Code of Federal Regulations as follows:

PART 109—EMPLOYMENT AUTHORIZATION—[REMOVED AND RESERVED]

1. Part 109 would be revised and redesignated as Subpart B of a new Part 274a to read as set forth below.

2. A new Part 274a would be added to read as follows:

PART 274a—CONTROL OF EMPLOYMENT OF ALIENS

Subpart A—Employer Requirements

Secs.

274a.1 Definitions.

274a.2 Verification of employment eligibility.

274a.3 Continuing employment of unauthorized aliens.

274a.4 Good faith defense.

274a.5 Use of labor through contract.

274a.6 State employment agencies.

274a.7 "Grandfather" provisions for employees hired prior to November 7, 1986.

274a.8 Prohibition on indemnity bonds.

274a.9 Enforcement procedures.

274a.10 Penalties

274a.11 Special rule for legalization, special agricultural worker and Cuban/Haitian entrant adjustment applicants.

Subpart B—Employment Authorization

274a.12 Classes of aliens eligible.

274a.13 Revocation of employment authorization.

Authority: Secs. 101, 1103, 274A of the Immigration and Nationality Act, 8 U.S.C. 1101, 1103, 1324A.

Subpart A—Employer Requirements

§ 274a.1 Definitions.

For the purpose of this chapter—

(a) The term "unauthorized alien" means, with respect to employment of an alien at a particular time, that the alien is not at that time either (1) an alien lawfully admitted for permanent residence, or (2) authorized by the Immigration and Naturalization Service to be employed;

(b) The term "entity" means any legal entity, including but not limited to, a corporation, partnership, joint venture, governmental body, agency, proprietorship, or association;

(c) The term "hire" means the actual commencement of employment of an employee for wages or other remuneration;

(d) The term "refer for a fee" means the act of sending or directing a person or transmitting documentation or information to another, directly or indirectly, with the intent to obtain employment for such person, for remuneration whether on a retainer or contingency basis;

(3) The term "recruit for a fee" means the act of soliciting a person, directly or

indirectly, with the intent of referring that person to another, for remuneration whether on a retainer or contingency basis;

(f) The term "employee" means an individual who provides services or labor for an employer for wages or other remuneration but shall not include independent contractors or those engaged in casual employment as stated in paragraph (h) of this section;

(g) The term "employer" means a person or entity, including anyone acting directly or indirectly in the interest thereof, who engages the services or labor of an employee to be performed in the United States for wages or other remuneration;

(h) The term "employment" means any service or labor performed by an employee for an employer within the United States, including service or labor performed on a U.S. vessel or aircraft which touches at a port in the United States, not including casual employment by individuals who provide domestic service in a private home that is sporadic, irregular or incidental.

(i) The term "State employment agency" means any State government unit designated to cooperate with the United States Employment Service in the operation of the public employment service system;

(j) The term "pattern or practice" means regular, repeated and intentional activities, but does not include isolated, sporadic or accidental acts.

§ 274a.2 Verification of employment eligibility.

(a) *General.* This section states the requirements and procedures persons or entities must comply with when hiring, recruiting or referring for a fee, individuals in the United States, or continuing to employ aliens knowing that the aliens are (or have become) unauthorized aliens. The Form I-9, Employment Eligibility Verification Form, has been designated by the Service as the form to be used in complying with the requirements of this section. Form I-9 need only be completed for individuals who are hired, recruited or referred for a fee for employment, after November 6, 1986. In conjunction with completing the Form I-9, an employer, recruiter or referrer for a fee, must examine documents that evidence both individual's identity and employment eligibility. The employer, recruiter or referrer for a fee and the individual must complete an attestation on the Form I-9 under penalty of perjury. However, if an individual attests to an employer, recruiter or referrer for a fee, that he/she is an alien who intends to apply or has applied for

benefits under the provisions of section 245A or 210A of the Act, then the individual is authorized to work in the United States until September 1, 1987 without providing the employer, recruiter or referrer for a fee, with documentary evidence of work authorization. In this case, the employer, recruiter or referrer for fee, shall indicate on the Form I-9, that the individual intends to apply or has applied for such benefits under section 245A or 210A of the Act. Employers, recruiters and referrers for a fee who fail to comply with the employment verification requirements set forth in § 274a.2(b) of this part shall be subject to penalties as stated in § 274a.10 of this part.

(b) *Employment verification requirements.*—(1) *Examination of documents and completion of Form I-9.* (i) An individual who is hired, recruited or referred for a fee for employment must: (A) complete the attestation and the other appropriate sections of the Form I-9 at the time of hiring, recruitment or referral for a fee for employment; and

(B) present to the employer documentation as set forth in paragraph (b)(1)(v) of this section establishing his/her identity and employment eligibility within the time limits set forth in paragraphs (b)(1)(ii) through (v) of this section. However, pursuant to the "Special Rule" set forth in § 274a.13 of this part, legalization, special agricultural worker and Cuban/Haitian entrant adjustment applicants are not required to present documentation establishing work authorization until after September 1, 1987.

(ii) An employer must within three business days of the hire: (A) Physically examine the documentation presented by the individual establishing identity and employment eligibility as set forth in (b)(1)(v) of this section; and

(B) complete the attestation and the other appropriate sections of the Form I-9.

(iii) An employer, who hires an individual for employment for a duration of less than three business days, must comply with paragraphs (b)(1)(ii)(A) through (B) of this section before the end of the employee's first working day.

(iv) A recruiter or referrer for a fee for employment must comply with paragraphs (b)(1)(ii)(A) through (B) of this section at the time of the recruitment or referral.

(v) The individual may present either an original document which establishes both employment authorization and identity, or an original document which establishes employment authorization

and a separate original document which establishes identity.

(A) The following documents are acceptable to evidence both identity and employment eligibility:

- (1) United States passport.
- (2) Certificate of United States Citizenship, INS Form N-560.
- (3) Certificate of Naturalization, INS Form N-550.

(4) An unexpired foreign passport which:

- (i) Contains an unexpired stamp therein which reads, "processed for I-551 . . ." or

(ii) Has attached thereto a Form I-94 bearing the same name as the employment authorization stamp, so long as the period of endorsement has not yet expired and the proposed employment is not in conflict with any restrictions or limitations identified on the Form I-94.

(5) Alien Registration Receipt Card, INS Form I-15, or Resident Alien, INS Form I-551, provided that it contains a photograph of the bearer.

(6) Temporary Resident Card, INS Form I-688, or Employment Authorization Card, INS Form I-688A, provided that it contains a photograph of the bearer.

(B) The following documents are acceptable to establish identity only:

(1) A State issued driver's license or identification card containing a photograph, or if the document does not contain a photograph, identifying information should be included such as: name, date of birth, sex, height, color of eyes and address;

(2) It will be necessary to designate other documents of identification which may be used in the case of a minor, or in a State which does not issue an identification card other than a driver's license. The Service desires to provide for the use of a wide range of documents to establish identity, and requests suggestions and comments from the public and particularly from federal, State, or local agencies which issue documents which could serve that purpose.

(C) The following are acceptable documents to establish employment authorization only:

(1) A social security card other than one not valid for employment purposes.

(2) An unexpired reentry permit, INS Form I-327.

(3) An unexpired Refugee Travel document, INS Form I-571.

(4) A Certification of Birth issued by the Department of State, Form FS-545.

(5) A Certification of Birth Abroad issued by the Department of State, Form DS-1350.

(6) An original or certified copy of a birth certificate issued by a State or recognized subdivision thereof establishing birth in a State.

(2) *Retention and Inspection of Form I-9.* (i) Form I-9 must be retained by an employer, recruiter or referrer for a fee for the following time periods: (A) In the case of recruiting or referring (without hiring) an individual for a fee, three years after the date of the recruitment or referral; or

(B) In the case of hiring of an individual, three years after the date of the hire or one year after the date the individual's employment is terminated, whichever is later.

(ii) Any person or entity required to retain Form I-9 in accordance with this section shall make such forms available for inspection upon oral request and presentation of credentials by an authorized officer of the Service or the Department of Labor. No subpoena, warrant, or advance notice shall be required for such inspection; however, a person or entity shall have three business days to comply with such a request. Any refusal or delay in presentation of the Form I-9 for inspection after three business days have elapsed is a violation of the retention requirements as set forth in § 274A(b)(3) of the Act.

(3) *Copying of documentation.* An employer, recruiter or referrer for a fee, may copy a document presented by an individual for purposes of complying with the verification requirements of paragraph (b) of this section only if the copy is retained with the Form I-9.

(4) *Limitation on use of Form I-9.* Form I-9 and any information contained in or appended to such Form I-9, may only be used by the Service for enforcement of: Sections 274A and 274B of the Act and 18 U.S.C. 1001, 1028, 1546, and 1621.

(c) *Employment verification requirements in the case of hiring an individual who was previously employed.* (1) When an employer hires an individual whom he/she has previously employed, and where the employer has completed the Form I-9 and complied with the verification requirements set forth in paragraph (b) of this section with regard to the individual, the employer shall inspect the Form I-9 which was previously completed and:

(i) If upon inspection of the Form I-9 relating to the individual, the employer determines that the individual is authorized to work, no additional verification or new Form I-9 need be completed where the individual is hired within one year of the initial execution of the Form I-9; or

(ii) If upon inspection of the Form I-9, the employer determines that the individual is no longer authorized to work in the United States, the employer shall not rehire the individual unless all the employment verification requirements set forth in paragraph (b) of this section are met.

(2) For purposes of retention of the Form I-9 by an employer for a previously employed individual hired pursuant to paragraph (c)(1) of this section, the employer shall retain the Form I-9 for a period of three years commencing from the date of the hire or one year after the date the individual's employment is terminated, whichever is later.

§ 274a.3 Continuing employment of unauthorized alien.

An employer who continues the employment of an employee hired after November 6, 1986 knowing that the employee is or has become an unauthorized alien with respect to such employment is in violation of section 274A(a)(2) of the Act.

§ 274a.4 Good faith defense.

An employer, recruiter or referrer for a fee for employment who shows good faith compliance with the employment verification requirements of paragraph (b) of this section shall have established a rebuttable affirmative defense that the person or entity has not violated section 274A(a)(1)(A) of the Act with respect to such hiring, recruiting or referral.

§ 274a.5 Use of labor through contract.

An employer who knowingly uses a contract, subcontract, or exchange entered into, renegotiated or extended after the date of enactment, to obtain labor or services of an unauthorized alien shall be considered to have hired the alien for employment in the United States in violation of section 274A(a)(1)(A) of the Act.

§ 274a.6 State employment agencies.

The Service desires to develop guidelines relating to role of state employment agencies in the issuance of certificates pursuant to section 274A(a)(5) of the Act, and requests the suggestions and comments of the public on this matter. A prime concern of the Service is the prevention of counterfeiting or misuse of such certificates while limiting the burden on state agencies in their issuance.

§ 274a.7 "Grandfather" provisions for employees hired prior to November 7, 1986.

(a) The verification of employment eligibility requirements and penalties provisions as set forth in §§ 274a.2(b)

and 274a.10 of this part shall not apply to:

(1) The hiring, recruiting or referring for a fee for employment of an individual for employment which occurred prior to November 7, 1986; or

(2) The continuing employment of an alien who was hired prior to November 7, 1986. An alien who falls within paragraph (a)(2) of this section shall be considered a "grandfather" employee.

(b) For purposes of this section, an alien who was hired prior to November 7, 1986 shall not lose his/her "grandfather" status if the alien:

(1) Is absent and returns to work after leave for study, illness or pregnancy; or (2) transfers from one location to another with the same employer.

(c) For purposes of this section, an alien who was hired prior to November 7, 1986 shall lose his/her "grandfather" status if the alien is:

(1) Terminated by the employer unless the "grandfather" employee is reinstated due to wrongful termination; or (2) excluded or deported from the United States or departs the United States under an order of voluntary departure.

(d) When an employer claims that he/she is not subject to the employment verification requirements of § 274a.2(b) of this part, with respect to an employee because the alien is a "grandfather" employee, the burden of proof shall be upon the employer to establish that the alien was hired prior to November 7, 1986, and that such alien did not lose such "grandfather" employee status under paragraph (c) of this section.

§ 274a.8 Prohibition of indemnity bonds.

(a) *General.* It is unlawful for a person or other entity, in hiring, recruiting or referring for a fee for employment of any individual, to require the individual to post a bond or security, to pay or agree to pay an amount, or otherwise to provide a financial guarantee or indemnity, against any potential liability arising under this part relating to such hiring, recruiting, or referring of the individual.

(b) *Penalty.* Any person or other entity who requires any individual to post a bond or security as stated in this section shall, after notice and opportunity for an administrative hearing in accordance with section 274A(e)(3)(B) of the Act, be subject to a civil fine of \$1,000 for each violation and to an administrative order requiring the return to the individual of any amounts received in violation of this section or, if the individual cannot be located, to the general fund of the Treasury.

§ 274a.9 Enforcement procedures.

(a) *Procedures for the filing of complaints.* Any person or entity having knowledge of a violation or potential violation of section 274A of the Act may submit a signed, written complaint in person or by mail to the Service office in the jurisdiction the business or residence of the potential violator is located. The signed, written complaint must contain sufficient information to identify both the complainant and the potential violator, including their names and addresses, and any other relevant information. Written complaints may be delivered either by certified mail to the appropriate Service office or by personally appearing before any immigration officer at a Service office.

(b) *Investigation.* The Service shall investigate only those written complaints which have a substantial probability of validity. The Service may investigate violations on its own initiative. An immigration officer conducting the investigation shall have reasonable access to examine evidence of the person or entity being investigated.

(c) *Determination.* If it is determined after investigation that the person or entity has violated section 274A of the Act, the Service shall issue and serve upon the alleged violator a Notice of Intent to Fine. Service of this Notice may be accomplished pursuant to section 103 of this chapter.

(d) *Notice of intent to fine.* Every determination or proceeding to assess administrative penalties under section 274A of the Act is commenced by the issuance of a Notice of Intent to Fine by the Service on Form I-762. The person or entity identified in the Notice of Intent to Fine shall be known as the respondent. The Notice of Intent to Fine may be issued by an officer defined in § 242.1 of this chapter.

(1) *Contents.* (i) The Notice of Intent to Fine will contain a concise statement of factual allegations informing the respondent of the act or conduct alleged to be in violation of law, a designation of the charge(s) against the respondent, the statutory provisions alleged to have been violated, and the penalty that will be imposed.

(ii) The Notice of Intent to Fine will provide the following advisals to the respondent:

(A) That the person or entity has the right to representation by counsel of his or her own choice at no expense to the government; (B) That any statement given may be used against the person or entity; (C) That the person or entity has the right to request a hearing before an Administrative Law Judge pursuant to 5

U.S.C. 554-557, and such request must be made within 30 days from the service of the Notice of Intent To Fine; (D) That the Service will issue a final order in 45 days if a request for hearing is not received and there will be no appeal of the final order.

§ 274a.10 Penalties.

(a) *General.* Except as provided herein, this section states the civil penalties that may be imposed for violations under section 274A of the Act. In determining the level of the penalties that should be imposed, a determination of more than one violation in the course of a single proceeding or determination will be counted as a single violation.

(1) A respondent determined by the Service (if the respondent fails to request a hearing), or an Administrative Law Judge, to have knowingly hired, recruited or referred for a fee an unauthorized alien for employment in the United States or to have knowingly continued to employ such an alien shall be subject to the following order:

(i) To cease and desist from such behavior, and
(ii) To pay a civil fine according to the following schedule:

(A) First violation—not less than \$250 and not more than \$2,000 for each unauthorized alien; or

(B) Second violation—not less than \$2,000 and not more than \$5,000 for each unauthorized alien; or

(C) More than two violations—not less than \$3,000 and not more than \$10,000 for each unauthorized alien.

(iii) To comply with the requirements of § 274a.2(b) of this part, and such other remedial action as is appropriate.

(2) A respondent determined by the Service (if the respondent fails to request a hearing) or by an Administrative Law Judge, to have failed to comply with the employment verification requirements as set forth in § 274a.2(b) of this part, shall be subject to a civil penalty in an amount of not less than \$100 and not more than \$1,000 for each individual with respect to whom such violation occurred. In determining the amount of the penalty, consideration shall be given to:

(i) The size of the business of the employer being charged,
(ii) The good faith of the employer,
(iii) The seriousness of the violation,
(iv) Whether or not the individual was an unauthorized alien, and
(v) The history of previous violations of the employer.

(3) Orders issued with respect to a respondent composed of distinct, physically separate subdivisions which do their own hiring, recruiting or referring for a fee for employment

(without reference to the practices of, or under the control of, or common control with another subdivision) such subdivisions shall be considered separate persons or entities.

§ 274a.11 Special rule for legalization, special agricultural worker and Cuban/Haitian entrant adjustment applicants.

An individual who claims to be eligible, and who intends to apply, or has applied, for benefits pursuant to section 245A or 210A of the Act, is not required to present an employer with documentary evidence of work authorization until after September 1, 1987. When an individual indicates to an employer that he/she claims to qualify for such benefits and that he/she intends to apply, or has applied, for temporary resident status, he or she shall provide a statement to that effect under oath or attestation on Form I-9 in lieu of documentation. The employer shall follow all of the employment verification procedures set forth in § 274a.2(b) of this part except that the employer shall note on the Form I-9 that the individual has stated his/her intention to seek such temporary resident status, instead of completing "List C—Employment Eligibility" on the employer portion of the I-9. After September 1, 1987, such individuals and employers will be required to fully comply with all provisions of § 274a.2(b) of this part. Nothing in this section shall be construed as constituting a grant of employment authorization by the Service to any unauthorized alien within the meaning of § 274a.12 of this part.

Subpart B—Employment Authorization**§ 274a.12 Classes of aliens eligible.**

(a) *Aliens authorized employment incident to status.* The employment authorization is limited solely to the extent and conditions described for the corresponding classifications in section 101(a)(15) of the Act, 8 CFR Part 214, 22 CFR Part 41 and 22 CFR 514.24. The following classes of aliens are authorized to be employed in the United States as a condition of their admission or subsequent change to one of the indicated classes, and specific authorization need not be requested:

(1) A lawful permanent resident alien.
(2) An alien admitted to the United States as a refugee under section 207 of the Act for the period of time in that status.

(3) An alien paroled into the United States as a refugee for the period of time in that status.

(4) An alien granted asylum under section 208 of the Act for the period of time in that status.

(5) An alien admitted to the United States as a nonimmigrant fiance or fiancee for the period of admission to the United States

(6) An alien admitted in one of the following classifications, or whose status has been changed to such classification under section 247 or 248 of the Act:

(i) A foreign government official (A-1) or (A-2).

(ii) An employee of a foreign government official (A-3).

(iii) A nonimmigrant visitor for business (B-1).

(iv) A nonimmigrant crewman (D-1).

(v) A nonimmigrant treaty trader or investor (E-1) or (E-2).

(vi) A representative of an international organization (G-1), (G-2), (G-3), or (G-4).

(vii) A personal servant of an employee or representative of an international organization (G-5).

(viii) A temporary worker or trainee (H-1), (H-2), (H-2A), or (H-3).

(ix) An information media representative (I).

(x) An exchange visitor (J-1).

(xi) An intra-company transferee (L-1).

(7) An alien who is a member of a nationality group who has been granted blanket extended voluntary departure.

(8) Applicants for benefits pursuant to sections 245A and 210 of the Act until September 1, 1987.

(b) *Aliens who must apply for work authorization.* Any alien within a class of aliens described in this paragraph must apply for work authorization to the district director in whose district the alien resides:

(1) Any alien maintaining a lawful nonimmigrant status in one or more of the following classes may be granted permission to be employed:

(i) Alien spouse or unmarried dependent son or daughter of a foreign government official (A-1) or (A-2) as provided in § 214.2(a)(2) of this title, or the dependent of an employee as provided by § 214.2(a)(3) of this title.

(ii) Alien nonimmigrant student (F-1) as provided in § 214.2(f) of this chapter.

(iii) Alien spouse or an unmarried dependent son or daughter of an officer or employee of an international organization (G-4) as provided in § 214.2(g) of this chapter.

(iv) Alien spouse or minor child or an exchange visitor (J-2) as provided in § 214.2(j) of this title.

(2) Any alien who has filed a non-frivolous application for asylum pursuant to Part 208 of this chapter may be granted permission to be employed for the period of time necessary to decide the case.

(3) Any alien who has properly filed an application for adjustment of status to permanent resident alien may be granted permission to be employed for the period of time necessary to decide the case.

(4) Any alien paroled into the United States temporarily for emergent reasons or for reasons deemed strictly in the public interest; provided, the alien establishes an economic need to work.

(5) Any alien who has applied to an Immigration Judge under § 242.17 of this chapter for suspension of deportation pursuant to section 244(a) of the Act may be granted permission to be employed for the period of time necessary to decide the case; provided, the alien establishes an economic need to work.

(6) Any deportable alien granted voluntary departure, either prior to hearing or after hearing, for reasons set forth in § 242.5(a)(2)(v), (vi), or (viii) of this chapter may be granted permission to be employed for that period of time prior to the date set for voluntary departure including any extension granted beyond such date. Factors which may be considered in granting employment authorization to an alien who has been granted voluntary departure:

(i) Length of voluntary departure granted;

(ii) Dependent spouse and/or children in the United States who rely on the alien for support;

(iii) Reasonable chance that legal status may ensue in the near future; and

(iv) Reasonable basis for consideration of discretionary relief.

(7) Any alien in whose case the district director recommends consideration of deferred action, an act of administrative convenience to the government which gives some cases lower priority; Provided, the alien establishes to the satisfaction of the district director that he/she is financially unable to maintain himself/herself and family without employment.

(8) Any excludable or deportable alien who has posted an appearance and delivery bond may be granted temporary employment authorization if

the district director determines that employment is appropriate under § 103.6(a)(2)(iii) of this chapter.

(c) *Basic criteria to establish economic necessity.* Title 45—Public Welfare, Poverty Income Guidelines, 45 CFR 1060.2 shall be used as the basic criteria to establish economic necessity for employment authorization requests where the alien's need to work is a factor. The applicant shall submit a signed statement listing his/her assets, income, and expenses as evidence of his/her economic need to work.

Permission to work granted on the basis of the applicant's statement may be revoked under § 274a.13 of this part upon a showing that the information contained in the statement was not true and correct.

§ 274a.13 Revocation of employment authorization.

(a) *Basis for revocation of employment authorization.* Employment authorization granted under § 274a.2(b) of this part may be revoked by the district director when it appears that one or more of the conditions upon which it was granted no longer exist, or for good cause shown.

(b) *Notice of intent to revoke employment authorization.* When a district director determines that employment authorization should be revoked, he/she shall serve notice of the reasons and the intention to revoke on the alien. The alien will be granted a period of fifteen days from the date of service of notice in which to submit evidence why the authorization should not be revoked. The decision by the district director shall be final and no appeal shall lie from the decision to revoke the authorization.

Dated: March 6, 1987.

Alan C. Nelson,

Commissioner, Immigration and Naturalization Service.

Attachment

Although not a part of the CFR, the following Immigration and Naturalization Service forms were developed as a result of the Immigration Reform and Control Act of 1986. The reproductions are not official forms and should not be copied or used in any way and are being included for informational purposes only.

BILLING CODE 4410-10-M

U.S. Department of Justice
Immigration and Naturalization Service

APPLICATION FOR STATUS AS A TEMPORARY RESIDENT
Under Section 245A of the Immigration and Nationality Act

I-687 Instructions - Page 1
(Conditions of Application)

Please carefully read all of the instructions: The fee will not be refunded.

Failure to follow instructions may require return of your application and delay final action. If your application is returned, no further action will be taken. You must resubmit your application with the requested documentation or information to renew processing.

Applications for status as a temporary resident as 1) an alien who illegally entered the United States prior to January 1, 1982 or 2) an alien who entered the United States as a nonimmigrant prior to January 1, 1982 and whose authorized stay expired before such date or whose unlawful status was known to the Immigration and Naturalization Service as of January 1, 1982 must be submitted or resubmitted by May 4, 1988. Failure to do so will make the applicant ineligible for the benefit sought.

1. Preparation of Application: A separate application for each applicant must be typewritten or printed legibly in ink. Applications by family members must be submitted together in order to receive the reduced family fee structure identified in item #5 of the instructions. The application must be completed in full. If extra space is needed to answer any item, attach a continuation sheet and indicate the item number. Various organizations and individuals (Qualified Designated Entities) have been designated by the Attorney General to assist applicants in the preparation of their applications. Your application must be submitted to the Immigration Legalization Office having jurisdiction over your place of residence.

2. Eligibility: An application may be filed by any alien who would qualify within the following guidelines. If you are not certain that you would qualify, you may contact a Qualified Designated Entity near your place of residence or an Immigration Legalization Office in your area. *The following aliens may be eligible for temporary resident status.*

(a) An alien who can establish that he/she entered the United States before January 1, 1982 and that he/she has resided continuously in the United States in an unlawful status since such date.

- (b) An alien who entered the United States as a nonimmigrant prior to January 1, 1982 and whose authorized stay expired before such date or whose unlawful status was known to the Government as of January 1, 1982 and who has resided continuously in the United States in an unlawful status since such date.

In order to be eligible for Temporary Resident status under paragraphs (a) and (b), the applicant must have been continuously physically present in the United States since the date of enactment of the Immigration Reform and Control Act of 1986 (November 6, 1986).

3. Ineligible Classes: The following classes of aliens are ineligible for temporary residence.

- (a) An alien who has been convicted of a felony or three or more misdemeanors committed in the United States.
- (b) An alien who has assisted in the persecution of any person or persons on account of race, religion, nationality, membership in a particular social group, or political opinion.
- (c) An alien who at any time was a nonimmigrant exchange visitor who is subject to the two-year foreign residence requirement unless the requirement has been satisfied or waived pursuant to the provisions of Section 212(e) of the Act.

4. Penalties for False Statements in Applications: Whoever files an application for adjustment of status under Section 245A of the Act and who knowingly and willfully falsifies, misrepresents, conceals or covers up a material fact or makes any false, fictitious, or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry will be subject to criminal prosecution and/or deportation.

Authority for Collecting this Information: The authority to prescribe this form is contained in the "Immigration Reform and Control Act of 1986." The information is necessary to determine whether a person is eligible for the immigration benefit sought. Information on race is requested in question #10 for statistical purposes only. You do not have to give this information. All other questions must be answered. Failure to do so may result in the denial of the application.

Confidentiality: The information provided in this application is confidential and may only be used to make a determination on the application or for enforcement of the penalties for false statements referred to in instruction #4. The information provided is subject to verification by the Immigration and Naturalization Service.

I-687 Instructions - Page 2

5. Fees: A fee of one hundred eighty-five dollars (\$185.00) for each application, or fifty dollars (\$50.00) for each application for a minor child (under 18 years of age) is required at the time of filing with the Immigration and Naturalization Service. The maximum amount payable by a family (husband, wife, and any minor children) shall be four hundred twenty dollars (\$420.00). The fee is not refundable regardless of the action taken on the application. A separate cashier's check or money order must be submitted for each application. *All fees must be submitted in the exact amount.* No cash or personnel checks will be accepted. The cashier's check or money order must be made payable to "Immigration and Naturalization Service" unless applicant resides in the Virgin Islands or Guam. (Applicants residing in the Virgin Islands make cashier's checks or money orders payable to "Commissioner of Finance of the Virgin Islands". Applicants residing in Guam make cashier's check or money order payable to "Treasurer, Guam".)

6. Photographs: Submit two (2) color photographs of yourself taken within thirty (30) days of the date of this application. These photos must have a white background, be glossy, unretouched, and not mounted; dimension of facial image should be about one inch from chin to top of hair; you should be shown in 3/4 frontal view showing right side of face with right ear visible; using pencil or felt pen, lightly print your name on the back of each photograph. Failure to comply with the above instructions will result in the return of the application without further action.

7. Fingerprints: A completed fingerprint card (Form FD-258) must be submitted by each applicant 14 years of age or older. Fingerprint cards with instructions for their completion are available at Qualified Designated Entity offices. Applicants may be fingerprinted by law enforcement offices, Outreach Centers, charitable and voluntary agencies, or other reputable persons or organizations. The fingerprint card (FD-258) on which the prints are submitted, the ink used, and the quality and classifiability of the prints must meet standards prescribed by the Federal Bureau of Investigation. The card must be signed by you in the presence of the person taking your fingerprints, who must then sign his/her name and enter the date in the spaces provided. It is important to furnish all the information called for on the card.

8. Interview: You will be required to be present for a personal interview by an officer of the Immigration and Naturalization Service. In most locations, interviews will be scheduled subsequent to receipt of the application.

9. Documents - General: All documents must be submitted in the original. If the return of original documents is desired, each must be accompanied by copies certified as true and correct by your representative or Qualified Designated Entity in the format prescribed in 8 CFR 204.2 (j)(1) or (2). Certified copies unaccompanied by original documents are unacceptable. All original documents submitted without certified copies become the property of the Attorney General and will be retained by the Service. Any document in a foreign language must be accompanied by a summary translation into English. A summary translation is a condensation or abstract of the document's text but includes all pertinent facts. The translator must certify that he/she is competent to translate into English and that the translation is accurate.

10. Documents to Establish Identity: The following list gives examples of the types of documents the Immigration and Naturalization Service will consider as evidence to establish your identity. This list is not all inclusive and other evidence may be considered if none of the following is available:

- Birth Certificate, Baptismal Certificate, or other evidence of birth
- Passport
- National Identification Card from country of origin
- Driver's License
- School Identification Card
- State Identification Card

11. Documents to Establish Admissibility:

- (a) Medical Report of Examination (Form I-693).
- (b) Evidence of Income: examples of documents which may be used as evidence of financial support or income include:
 - Letters from employers which illustrate full-time employment.
 - W-2 Tax Records or other wage records.
 - Bank statements or evidence of other assets.
 - Form I-134 (Affidavit of Support) completed by a responsible person in the United States.
 - Any other evidence to establish that the applicant is not likely to become a public charge.
- (c) An application for a Waiver of Grounds of Excludability (Form I-690) may be required if you answer any of the items 39 through 43 in the affirmative.

12. Documents to Establish Residence: Examples of documents which may be submitted to prove continuity of residence include:

- Leases
- Rent Receipts
- Employer, union or other business records
- Birth certificates of children born in the United States
- Automobile license receipts
- Vehicle registrations
- Deeds
- Mortages
- Utility bill receipts
- Installment loan records
- Church records
- Medical records

Letters from landlords should include the landlord's present address and the beginning and terminating dates of the applicant's residence. Letters from employers' organizations or churches should be on official stationery and include relevant dates, the organization seal (if any) and the signer's name and title.

U.S. Department of Justice
Immigration and Naturalization Service

Application for Status as a Temporary Resident
(Under Section 245A of the Immigration and Nationality Act)

OMB #1115-0133

Please begin with item #1, after carefully reading the instructions.

The block below is for Government Use Only.

Name and Location (City or Town) of Qualified Designated Entity	Fee Stamp
	Fee Receipt No. (This application)
	Principal Applicant's File No. A -
Qualified Designated Entity I.D. No. A -	File No. (This applicant)

Applicant: Do not write above this line. See instructions before filling in application. If you need more space to answer fully any question on this form, use a separate sheet and identify each answer with the number of the corresponding question. *Fill in with typewriter or print in block letters in ink.*

1. I hereby apply for status as indicated by the block checked below (check block A or B).				
<input type="checkbox"/> A Temporary Residence as an alien who illegally entered the U.S. prior to January 1, 1982. <input type="checkbox"/> B Temporary Residence as an alien who entered the U.S. as a nonimmigrant prior to January 1, 1982 and whose authorized stay expired before such date or whose unlawful status was known to the Government as of January 1, 1982.				
2. Family Name-(Last Name in CAPITAL Letters) (First Name) (Middle Name)			3. Date of Birth (Month/Day/Year)	
4. Other Names Used or Known by (Including maiden name, if married)			5. Telephone Numbers (Include Area Codes) Home: Work:	
6. Home Address in the U.S. (No. and Street)		(Apt. No.)	(City)	(State) (ZIP Code)
7. Mailing Address in the U.S. (if different from #6)		(Apt. No.)	(City)	(State) (ZIP Code)
8. Last Address outside the U.S. (City or Town)		(County, Province or State)		(Country)
9. Sex	<input type="checkbox"/> Male	10. Race	<input type="checkbox"/> Asian or Pacific Islander	<input type="checkbox"/> Black, not of Hispanic origin <input type="checkbox"/> Other (specify below)
	<input type="checkbox"/> Female		<input type="checkbox"/> Hispanic	<input type="checkbox"/> White, not of Hispanic origin
11. Marital Status			<input type="checkbox"/> Never Married	<input type="checkbox"/> Divorced
			<input type="checkbox"/> Now Married	<input type="checkbox"/> Separated <input type="checkbox"/> Widowed
13. Place of Birth (City or Town)		(County, Province or State)		(Country)
14. Have you previously applied for temporary residence as a legalization applicant?			15. Do you have any other record with I&NS? <input type="checkbox"/> No <input type="checkbox"/> Yes [If "Yes" give number(s)] A - _____ Other _____	
			<input type="checkbox"/> With visa (visitor, student, etc.) specify _____	
			<input type="checkbox"/> Without visa	
16. When did you last come to the U.S.? (Month/Day/Year)		17. Manner of Entry (Visitor, Student, Crewman, etc.) <input type="checkbox"/> With visa (visitor, student, etc.) specify _____		
		<input type="checkbox"/> Without visa		
18. Place of Last Entry		19. List all Social Security Numbers used. (1) _____ (3) _____ (2) _____ (4) _____		
<input type="checkbox"/> U.S. Port of entry (City and State) _____				
<input type="checkbox"/> Border - Not through port (State) _____				
20. Mother's Name (Maiden) (Last) (First) <input type="checkbox"/> Living		21. Father's Name (Last) (First) <input type="checkbox"/> Living		
		<input type="checkbox"/> Deceased (year) _____		
		<input type="checkbox"/> Deceased (year) _____		

34. To assist in establishing the required residence, please list all affiliations or associations with clubs, organizations, churches, unions, businesses, etc.

Name of Organization	Location	From (Month/Year)	To (Month/Year)

35. Absences from the United States since entry. (List most recent absence first and list absences back to January 1, 1982).

Country	Purpose of Trip	From (Month/Year)	To (Month/Year)

36. Employment in the United States since first entry. (List present or most recent first and list back to date of entry; if none since entry, write "None".)

Full Name and Address of Employer (with ZIP Code) (or Self employed and business address)	Your Occupation	Annual Wages	Wages per Hour	From (Month/Year)	To (Month/Year)

37. I have registered under the Military Selective Service Act. My Selective Service No. is _____
 I am a male over the age of 17 and under the age of 26 required to register under the Military Selective Service Act and have not done so. I wish to register at this time. SSS Form 1 is attached.
 I am a male born after 1959 and over the age of 26 and cannot now register.
 I am exempt from Selective Service Registration either because I am a female or I was born before 1960.

38. I <input type="checkbox"/> have	I <input type="checkbox"/> have not assisted in the persecution of any person or persons on account of race, religion, nationality, membership in a particular social group or political opinion.
39. I <input type="checkbox"/> have	I <input type="checkbox"/> have not been treated for a mental disorder, drug addiction or alcoholism.
40. I <input type="checkbox"/> have	I <input type="checkbox"/> have not been arrested, convicted or confined in a prison.
41. I <input type="checkbox"/> have	I <input type="checkbox"/> have not been the beneficiary of a pardon, amnesty, rehabilitation decree, other act of clemency or similar action.
42. I <input type="checkbox"/> have	I <input type="checkbox"/> have not received public assistance from any source, including, but not limited to, the United States Government, any state, county, city or municipality. (If you have, explain; including the name(s) and Social Security number(s) used.)

43. Applicants for status as Temporary Residents must establish that they are admissible to the United States. Except as otherwise provided by law, aliens within any of the following classes are not admissible to the United States and are therefore ineligible for status as Temporary Residents.
- A. Aliens who have committed or who have been convicted of a crime involving moral turpitude (does not include minor traffic violations).
 - B. Aliens who have been engaged in or who intend to engage in any commercialized sexual activity.
 - C. Aliens who are or at any time have been anarchists, or members or affiliated with any Communist or other totalitarian party, including any subdivision or affiliate thereof.
 - D. Aliens who have advocated or taught, either by personal utterance, or by means of any written or printed matter, or through affiliation with an organization:
 - 1) Opposition to organized government;
 - 2) The overthrow of government by force or violence;
 - 3) The assaulting or killing of government officials because of their official character;
 - 4) The unlawful destruction of property;
 - 5) Sabotage; or,
 - 6) The doctrines of world communism, or the establishment of a totalitarian dictatorship in the United States.
 - E. Aliens who intend to engage in activities prejudicial to the national interests or unlawful activities of a subversive nature.
 - F. Aliens who, during the period beginning on March 23, 1933, and ending on May 8, 1945, under the direction of, or in association with:
 - 1) The Nazi government in Germany;
 - 2) Any government in any area occupied by the military forces of the Nazi government in Germany;
 - 3) Any government established with the assistance or cooperation of the Nazi government of Germany;
 - 4) Any government which was an ally of the Nazi government of Germany;
- ordered, incited, assisted or otherwise participated in the persecution of any person because of race, religion, national origin, or political opinion.

Do any of the above classes apply to you? No

- G. Aliens who have been convicted of a violation of any law or regulation relating to narcotic drugs or marihuana, or who have been illicit traffickers in narcotic drugs or marihuana.
 - H. Aliens who have been involved in assisting any other aliens to enter the United States in violation of the law.
 - I. Aliens who have applied for exemption or discharge from training or service in the Armed Forces of the United States on the ground of alienage and who have been relieved or discharged from such training or service.
 - J. Aliens who are mentally retarded, insane, or who have suffered one or more attacks of insanity.
 - K. Aliens afflicted with psychopathic personality, sexual deviation, mental defect, narcotic drug addiction, chronic alcoholism or any dangerous contagious disease.
 - L. Aliens who have a physical defect, disease or disability affecting their ability to earn a living.
 - M. Aliens who are paupers, professional beggars or vagrants.
 - N. Aliens who are polygamists or advocate polygamy.
 - O. Aliens likely to become a public charge.
 - P. Aliens who have been excluded from the United States within the past year, or who at any time within 5 years have been deported from the United States.
 - Q. Aliens who have procured or have attempted to procure a visa by fraud or misrepresentation.
 - R. Aliens who are former exchange visitors who are subject to but have not complied with the two-year foreign residence requirement.
- Yes (If "Yes", explain on a separate sheet of paper.)

44. If your native alphabet is in other than Roman letters, write your name in your native alphabet.		45. Language of native alphabet	
46. Signature of Applicant - I CERTIFY, under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. I hereby consent and authorize the Service to verify the information provided, and to conduct police, welfare and other record checks pertinent to this application.		47. Date (Month/Day/Year)	
48. Signature of person preparing form, if other than applicant. I DECLARE that this document was prepared by me at the request of the applicant and is based on all information of which I have any knowledge.		49. Date (Month/Day/Year)	
50. Name and Address of person preparing form, if other than applicant (type or print).		51. Occupation of person preparing form	
QUALIFIED DESIGNATED ENTITY USE ONLY			
52. Reviewed by (Print or Type Name)	53. Signature	54. Date	
IMMIGRATION AND NATURALIZATION SERVICE USE ONLY			
55. Recommendation: Temporary Residence <input type="checkbox"/> Approved <input type="checkbox"/> Denied	56. Waiver of Excludability under Section 212 (a) _____ is <input type="checkbox"/> Approved <input type="checkbox"/> Denied		
57. Class of Admission	58. Place of Adjustment	59. Date of Adjustment	
60. Recommended by (Print or type Name and Title)	61. Signature	62. ID No.	63. Date
64. Final Action: Temporary Residence <input type="checkbox"/> Approved <input type="checkbox"/> Denied	65. Director Regional Processing Facility	66. ID. No.	67. Date

U.S. Department of Justice
Immigration and Naturalization Service

Application for Temporary Resident Status as a Special Agricultural Worker (SAW)
(Section 210 of the Immigration and Nationality Act)

I-700 Instructions - Page 1
(Conditions of Application)

Please carefully read all of the instructions: The fee will not be refunded.

Failure to follow instructions may require return of your application and delay final action. If your application is returned, no further action will be taken. You must resubmit your application with the requested documentation or information to renew processing.

Applications for temporary resident status as a special agricultural worker must be submitted (or resubmitted) by November 30, 1988. Failure to do so will make the applicant ineligible for the benefit sought.

1. Preparation of Application and Filing: A separate application for each applicant must be typewritten or printed legibly in ink. Applications by family members must be submitted together in order to receive the reduced family fee structure identified in item #5 of the instructions. The application must be completed in full. If extra space is needed to answer any item, attach a continuation sheet and indicate the item number. Various organizations and individuals (Qualified Designated Entities) have been designated by the Attorney General to assist applicants in the preparation of their applications.

Applicants who have been in the United States since November 6, 1986 may file their applications in the United States with a legalization office of the Immigration and Naturalization Service or with a Qualified Designated Entity. All others must file their applications outside the United States at a location designated by the nearest American Consulate.

2. Penalties for False Statements in Applications: Whoever files an application for adjustment of status under Section 210 of the Act and who knowingly and willfully falsifies, conceals or covers up a material fact or makes any false, fictitious, or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry or creates or supplies a false writing or document for use in making such an application will be subject to criminal prosecution and/or deportation.

Authority for Collecting this Information: The authority to prescribe this form is contained in the "Immigration Reform and Control Act of 1986." The information is necessary to determine whether a person is eligible for the immigration benefit sought. Information on race is requested in question #9 for statistical purposes only. You do not have to give this information. All other questions must be answered. Failure to do so may result in the denial of the application.

Confidentiality: The information provided in this application is confidential and may only be used to make a determination on the application or for enforcement of the penalties for false statements referred to in instruction #2. The information provided is subject to verification by the Immigration and Naturalization Service.

I-700

I-700 Instructions - Page 2

5. **Fees:** A fee of one hundred eighty-five dollars (\$185.00) for each application, or fifty dollars (\$50.00) for each application for a minor child (under 18 years of age) is required at the time of filing with the Immigration and Naturalization Service. The maximum amount payable by a family (husband, wife, and any minor children) shall be four hundred twenty dollars (\$420.00). The fee is not refundable regardless of the action taken on the application. A separate cashier's check or money order must be submitted for each application. **All fees must be submitted in the exact amount.** No cash or personal checks will be accepted. The cashier's check or money order must be made payable to "Immigration and Naturalization Service" unless applicant resides in the Virgin Islands or Guam. (Applicants residing in the Virgin Islands make cashier's checks or money orders payable to "Commissioner of Finance of the Virgin Islands". Applicants residing in Guam make cashier's check or money order payable to "Treasurer, Guam".)
6. **Photographs:** Submit two (2) color photographs of yourself taken within thirty (30) days of the date of this application. These photos must have a white background, be glossy, unretouched, and not mounted; dimension of facial image should be about one inch from chin to top of hair; you should be shown in 3/4 frontal view showing right side of face with right ear visible; using pencil or felt pen, lightly print your name on the back of each photograph. Failure to comply with the above instructions will result in the return of the application without further action.
7. **Fingerprints:** A completed fingerprint card (Form FD-258) must be submitted by each applicant 14 years of age or older. Fingerprint cards with instructions for their completion are available at Qualified Designated Entity offices. Applicants in the United States may be fingerprinted by law enforcement offices, Qualified Designated Entities, or other reputable persons or organizations. Applicants outside of the United States may be fingerprinted at an American Consulate. The fingerprint card (FD-258) on which the prints are submitted, the ink used, and the quality and classifiability of the prints must meet standards prescribed by the Federal Bureau of Investigation. The card must be signed by you in the presence of the person taking your fingerprints, who must then sign his/her name and enter the date in the spaces provided. It is important to furnish all the information called for on the card.
8. **Interview:** You will be required to be present for a personal interview by either an officer of the Immigration and Naturalization Service or an American consul. In most locations, interviews will be scheduled subsequent to receipt of the application.
9. **Documents - General:** All documents must be submitted in the original. If the return of original documents is desired, each must be accompanied by copies certified as true and correct by your representative or designated Qualified Designated Entity in the format prescribed in 8 CFR 204.2 (j)(1) or (2). Certified copies unaccompanied by original documents are unacceptable. All original documents submitted without certified copies become the property of the Attorney General and will be retained by the Service. Any document in a foreign language must be accompanied by a summary translation into English. A summary translation is a condensation or abstract of the document's text but includes all pertinent facts. The translator must certify that he/she is competent to translate into English and that the translation is accurate.

10. **Documents to Establish Identity:** The following list gives examples of the types of documents the Immigration and Naturalization Service will consider as evidence to establish your identity. This list is not all inclusive and other evidence may be considered if none of the following is available:

- Birth Certificate, Baptismal Certificate, or other evidence of birth
- Passport
- National Identification Card from country or origin
- Driver's License
- School Identification Card
- State Identification Card

11. **Documents to Establish Admissibility:**

- (a) Medical Report of Examination (Form I-693).
- (b) Evidence of Income: During periods of residence in the United States examples of documents which may be used as evidence of financial support or income include:
 - Documents listed in item #13.
 - Letters from employers which illustrate full-time employment.
 - W-2 Tax Records or other wage records.
 - Bank statements or evidence of other assets.
 - Form I-134 (Affidavit of Support) completed by a responsible person in the United States.
 - Any other evidence to establish that the applicant is not likely to become a public charge.
- (c) An application for a Waiver of Grounds of Excludability (Form I-690) may be required if you answer any of the items 26 through 29 in the affirmative.

12. **Documents to Establish Residence:** Examples of documents which may be submitted to establish residence in the United States during the requisite period(s) include:

- Employment records
- Leases
- Birth certificates of children born in the United States
- Church records
- Medical records

13. **Documents to Establish Qualifying Employment:** Examples of documents which may be submitted to prove employment as a Seasonal Agricultural Worker include:

- Government employment records
- Employment records kept by growers, their foremen, farm labor contractors, unions.
- Affidavits executed under oath by persons with specific knowledge of the applicant's employment.
- Other reliable documentation as the alien may provide, such as pay stubs, work receipts and worker identification cards.

Documentation provided by Special Agricultural Workers is subject to employer corroboration.

U.S. Department of Justice
Immigration and Naturalization Service

Application for Temporary Resident Status as a Special Agricultural Worker (Section 210 of the Immigration and Nationality Act) OMB #1115-0131

Please begin with item #1, after carefully reading the instructions.

The block below is for Government Use Only.

Name and Location (City or Town) of Qualified Designated Entity	Fee Stamp
	Fee Receipt No. (This application)
	Principal Applicant's File No. A -
Qualified Designated Entity I.D. No.	File No. (This applicant) A -

Applicant: Do not write above this line. See instructions before filling in application. If you need more space to answer fully any question on this form, use a separate sheet and identify each answer with the number of the corresponding question. *Fill in with typewriter or print in block letters in ink.*

1 I hereby apply for status as indicated by the block checked below (check block A or B).

- A Group I: Temporary Residence as an alien who has performed seasonal agricultural services in the U.S. for at least 90 days during each of the 12 month periods ending on May 1, 1984, 1985, and 1986.
- B Group II: Temporary Residence as an alien who has performed seasonal agricultural services in the U.S. for at least 90 days during the 12 month period ending on May 1, 1986.

2 Family Name (Last Name in CAPITAL Letters)	(First Name)	(Middle Name)	3. Date of Birth (Month/Day/Year)	
4 Other Names Used or Known by (Including maiden name, if married)			5. Telephone Numbers (Include Area Codes) Home: Work:	
6 Address (No. and Street)	(Apt. No.)	(Town or City)	(State/Country)	(ZIP/Postal Code)
7 Last Address outside the U.S. (City or Town)	(County, Province or State)		(Country)	
8 Sex <input type="checkbox"/> Male	9 Race <input type="checkbox"/> Asian or Pacific Islander	<input type="checkbox"/> Black, not of Hispanic origin	<input type="checkbox"/> Other (specify below)	
<input type="checkbox"/> Female	<input type="checkbox"/> Hispanic	<input type="checkbox"/> White, not of Hispanic origin		
10 Marital Status <input type="checkbox"/> Now Married	<input type="checkbox"/> Never Married	<input type="checkbox"/> Divorced	11. Country of Citizenship	
	<input type="checkbox"/> Separated	<input type="checkbox"/> Widowed		
12 Place of Birth (City or Town)	(County, Province or State)		(Country)	
13. Have you previously applied for temporary residence as a Special Agricultural Worker? <input type="checkbox"/> No <input type="checkbox"/> Yes (if "Yes" give date, place of filing, and final disposition, if known)			14. Do you have any other record with I&NS? <input type="checkbox"/> No <input type="checkbox"/> Yes (If "Yes" give number(s)) A - _____ Other _____	
15. When did you last come to the U.S.? (Month/Day/Year)			16. Manner of Entry (Visitor, Student, Crewman, etc.) <input type="checkbox"/> With visa (visitor, student, etc.) specify _____ <input type="checkbox"/> Without visa	
17. Place of Last Entry <input type="checkbox"/> U.S. Port of entry (City and State) _____ <input type="checkbox"/> Border - Not through port (State) _____			18. List all Social Security Numbers used. (1) _____ (3) _____ (2) _____ (4) _____	
19. Mother's Name (Maiden) (Last) (First) <input type="checkbox"/> Living <input type="checkbox"/> Deceased (year) _____			20. Father's Name (Last) (First) <input type="checkbox"/> Living <input type="checkbox"/> Deceased (year) _____	

29. Applicants for status as Temporary Residents must establish that they are admissible to the United States. Except as otherwise provided by law, aliens within any of the following classes are not admissible to the United States and are therefore ineligible for status as Temporary Residents.
- A. Aliens who have committed or who have been convicted of a crime involving moral turpitude (does not include minor traffic violations).
 - B. Aliens who have been engaged in or who intend to engage in any commercialized sexual activity.
 - C. Aliens who are or at any time have been anarchists, or members of or affiliated with any Communist or other totalitarian party, including any subdivision or affiliate thereof.
 - D. Aliens who have advocated or taught, either by personal utterance, or by means of any written or printed matter, or through affiliation with an organization:
 - 1) Opposition to organized government;
 - 2) The overthrow of government by force or violence;
 - 3) The assaulting or killing of government officials because of their official character;
 - 4) The unlawful destruction of property;
 - 5) Sabotage, or;
 - 6) The doctrines of world communism, or the establishment of a totalitarian dictatorship in the United States.
 - E. Aliens who intend to engage in activities prejudicial to the national interests or unlawful activities of a subversive nature.
 - F. Aliens who, during the period beginning on March 23, 1933, and ending on May 8, 1945, under the direction of, or in association with:
 - 1) The Nazi government in Germany;
 - 2) Any government in any area occupied by the military forces of the Nazi government in Germany;
 - 3) Any government established with the assistance or cooperation of the Nazi government of Germany;
 - 4) Any government which was an ally of the Nazi government of Germany,
- ordered, incited, assisted or otherwise participated in the persecution of any person because of race, religion, national origin, or political opinion.

Do any of the above classes apply to you? No

- G. Aliens who have been convicted of a violation of any law or regulation relating to narcotic drugs or marihuana, or who have been illicit traffickers in narcotic drugs or marihuana.
 - H. Aliens who have been involved in assisting any other aliens to enter the United States in violation of the law.
 - I. Aliens who have applied for exemption or discharge from training or service in the Armed Forces of the United States on the ground of alienage and who have been relieved or discharged from such training or service.
 - J. Aliens who are mentally retarded, insane, or who have suffered one or more attacks of insanity.
 - K. Aliens afflicted with psychopathic personality, sexual deviation, mental defect, narcotic drug addiction, chronic alcoholism or any dangerous contagious disease.
 - L. Aliens who have a physical defect, disease or disability affecting their ability to earn a living.
 - M. Aliens who are paupers, professional beggars or vagrants.
 - N. Aliens who are polygamists or advocate polygamy.
 - O. Aliens likely to become a public charge.
 - P. Aliens who have been excluded from the United States within the past year, or who at any time within 5 years have been deported from the United States.
 - Q. Aliens who have procured or have attempted to procure a visa by fraud or misrepresentation.
 - R. Aliens who are former exchange visitors who are subject to but have not complied with the two-year foreign residence requirement.
- Yes (If "Yes", explain on a separate sheet of paper.)

30. If your native alphabet is in other than Roman letters, write your name in your native alphabet.		31. Language of native alphabet	
32. Signature of Applicant - I CERTIFY, under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. I hereby consent and authorize the Service to verify the information provided, and to conduct police, welfare and other record checks pertinent to this application.		33. Date (Month/Day/Year)	
34. Signature of person preparing form, if other than applicant. I DECLARE that this document was prepared by me at the request of the applicant and is based on all information on which I have any knowledge.		35. Date (Month/Day/Year)	
36. Name and Address of person preparing form, if other than applicant (type or print).		37. Occupation of person preparing form	
QUALIFIED DESIGNATED ENTITY USE ONLY			
38. Reviewed by (Print or Type Name)	39. Signature	40. Date	
IMMIGRATION AND NATURALIZATION SERVICE USE ONLY			
41. Recommendation: Temporary Residence	42. Waiver of Excludability under Section 212 (a) _____ is <input type="checkbox"/> Approved <input type="checkbox"/> Denied		
43. Class of Admission	44. Place of Adjustment	45. Date of Adjustment	
46. Recommended by (Print or type Name and Title)	47. Signature	48. ID No.	49. Date
50. Final Action: Temporary Residence	51. Director Regional Processing Facility	52. ID No.	53. Date
<input type="checkbox"/> Approved <input type="checkbox"/> Denied			

U.S. Department of Justice
Immigration and Naturalization Service

Medical Examination of Aliens Seeking
Adjustment of Status (P.L. 99-603)

Instructions

To Alien Applying for Adjustment of Status

A medical examination is necessary as part of your application for adjustment of status. Please communicate immediately with one of the physicians on the attached list to arrange for your medical examination, which must be completed before your status can be adjusted. The purpose of the medical examination is to determine if you have certain health conditions which may need further followup. All expenses in connection with this examination must be paid by you. The examining physician may refer you to your personal physician or a local public health department and you must comply with some health followup or treatment recommendations for certain health conditions before your status will be adjusted.

This form should be presented to the examining physician. You must sign the form in the presence of the examining physician. *The law provides severe penalties for knowingly and willfully falsifying or concealing a material fact or using any false documents in connection with this medical examination.*

To Physician Performing the Examination

Please medically examine for adjustment of status the individual presenting this form. The medical examination should be performed according to the U.S. Public Health Service "Guidelines for the Medical Examination of Aliens in the United States and Supplement" which have been provided to you separately.

If the applicant is free of medical defects listed in Section 212(a) of the Immigration and Nationality Act, endorse the form in the space provided. While in your presence, the applicant must also sign the form in the space provided. You should retain one copy for your files and return all other copies in a sealed envelope to the applicant for presentation at the immigration interview.

If the applicant has a health condition which requires followup as specified in the "Guidelines for Medical Examination of Aliens in the United States and Supplement", complete the referral information on the pink copy of the medical examination form, and advise the applicant that appropriate followup must be obtained before medical clearance can be granted. Retain the blue copy of the form for your files and return all other copies to the applicant in a sealed envelope. The applicant should return to you when the necessary followup has been completed for your final verification and signature. *Do not sign the form until the applicant has met health followup requirements. All medical documents, including chest x-ray films if a chest x-ray examination was performed, should be returned to the applicant upon final medical clearance.*

To Physician Providing Health Followup

The individual presenting this form has been found to have a medical condition(s) requiring resolution before medical clearance for adjustment of status can be granted. Please evaluate the applicant for the condition(s) identified. The requirements for clearance are outlined on the reverse of this page. When the individual has completed clearance requirements, please sign the form in the space provided and return the medical examination form to the applicant.

Medical Examination and Health Information

A medical examination is necessary as part of your application for adjustment of status under the Immigration Reform and Control Act of 1986. You should go for your medical examination as soon as possible. The organization or person who gave you your application packet can help you arrange the medical examination. You will have to choose a doctor from a list you will be given. The list will have the names of doctors or clinics in your area that have been approved by the Immigration and Naturalization Service for this examination. You must pay for the examination. The cost may be different from place to place, but should be in the \$30 - \$60 range. If you become a temporary legal resident and later apply to become a permanent resident, you will need to have another medical examination at that time.

The purpose of the medical examination is to find out if you have certain health conditions which may need further followup. The doctor will examine you for certain physical and mental health conditions. You will have to take off your clothes. If you need more tests because of a condition found during your medical examination, the doctor may send you to your own doctor or to the local public health department. For some conditions, before you can become a temporary or permanent resident, you will have to show that you have followed the doctor's advice to get more tests or take treatment.

One of the conditions you will be tested for is tuberculosis. If you are 15 years of age or older, you may choose to be tested for tuberculosis with either a chest x-ray or a skin test (an injection into the skin on your arm). The skin test costs less than a chest x-ray examination. If you choose the skin test you will have to return in 2 - 3 days to have it checked. If you do not have any reaction to the skin test you will not need any more tests for tuberculosis. If you do have any reaction to the skin test, you will then need to go ahead and have a chest x-ray examination too. If the doctor thinks you are infected with tuberculosis, you may have to go to the local health department and more tests may have to be done. The doctor will explain these to you.

If you are 14 years of age or younger, you will not need to have a test for tuberculosis unless a member of your immediate family has chest x-ray findings that may be tuberculosis. If you are in this age group and you do have to be tested for tuberculosis, you too may choose either the chest x-ray or the skin test.

You must also have a blood test for syphilis if you are 15 years of age or older.

If you have any records of immunizations (vaccinations), you should bring them to show to the doctor. This is especially important for pre-school and school-age children. The doctor will tell you if any more immunizations are needed, and where you can get them (usually at your local public health department). It is important for your health that you follow the doctor's advice and go to get any immunizations.

U.S. Department of Justice
Immigration and Naturalization Service

OMB #1115-0134
Medical Examination of Aliens Seeking
Adjustment of Status (P. L. 99-603)

(Please Type or Print Clearly)
I certify that on the date shown I examined:

NAME: LAST	FIRST	MI	DATE OF EXAMINATION MO DA YR	FILE NO.
			DATE OF BIRTH: MO DA YR	COUNTRY OF BIRTH:
ADDRESS: STREET			CITY	STATE ZIP

GENERAL PHYSICAL EXAMINATION

I examined specifically for evidence of the conditions listed below. My examination revealed:

No apparent defect, disease, or disability The conditions listed below were found (check boxes that apply)

CLASS A Conditions			CLASS B Conditions		
<input type="checkbox"/> Chancroid	<input type="checkbox"/> Hansen's Disease, Infectious	<input type="checkbox"/> Tuberculosis, Active	<input type="checkbox"/> Tuberculosis, Not Active		
<input type="checkbox"/> Gonorrhea	<input type="checkbox"/> Lymphogranuloma Venereum	<input type="checkbox"/> Other: _____	<input type="checkbox"/> Hansen's Disease, Not Infectious		
<input type="checkbox"/> Granuloma Inguinale	<input type="checkbox"/> Syphilis, Infectious		<input type="checkbox"/> Other Physical Defect, Disease or Disability: _____		
<input type="checkbox"/> Mental Retardation	<input type="checkbox"/> Previous Occurrence of One or More Attacks of Insanity	<input type="checkbox"/> Mental Defect			
<input type="checkbox"/> Insanity	<input type="checkbox"/> Psychopathic Personality	<input type="checkbox"/> Narcotic Drug Addiction			
<input type="checkbox"/> Sexual Deviation		<input type="checkbox"/> Chronic Alcoholism			

EXAMINATION FOR TUBERCULOSIS

TUBERCULIN SKIN TEST

FROM Doctor _____
(Please Print)

REACTION mm MO DA YR
 NO REACTION NOT DONE DATE READ

CHEST X-RAY REPORT

FROM Doctor _____
(Please Print)

NORMAL MO DA YR
 ABNORMAL NOT DONE DATE READ

SEROLOGIC TEST FOR SYPHILIS

TEST TYPE _____
FROM Doctor _____
(Please Print)

REACTIVE TITER MO DA YR
 NONREACTIVE DATE READ

TEST TYPE _____
FROM Doctor _____
(Please Print)

REACTIVE TITER MO DA YR
 NONREACTIVE DATE READ

IMMUNIZATION DETERMINATION (DTP, OPV, MMR, Td - Refer to PHS Guidelines for recommendations.)

Applicant is current for recommended age-specific immunizations Applicant is not current for recommended age-specific immunizations and I have encouraged that appropriate immunizations be obtained

REMARKS:

CIVIL SURGEON REFERRAL FOR FOLLOW-UP OF MEDICAL CONDITION

The alien named above has applied for adjustment of status. A medical examination conducted by me identified the conditions above which require resolution before medical clearance is granted or for which the alien may seek medical advice. Please provide follow-up services or refer the alien to an appropriate health care provider. The actions necessary for medical clearance are detailed on the reverse of this form.

FOLLOW-UP INFORMATION

The alien named above has complied with recommended health follow-up. _____

SIGNATURE TITLE MO DA YR

[REDACTED]

APPLICANT CERTIFICATION

I certify that the information contained in this form refers to me. _____

SIGNATURE TITLE MO DA YR

[REDACTED]

CIVIL SURGEON CERTIFICATION

My examination showed the applicant to have met the medical examination and health follow-up requirements for adjustment of status. _____

SIGNATURE TITLE MO DA YR

[REDACTED]

The Immigration and Naturalization Service is authorized to collect this information under the provisions of the Immigration Reform and Control Act of 1986, Public Law 99-603. The individually identified data requested is required in order for a proper evaluation to be made of your health status, and may be shared with health departments and other public health or cooperating medical authorities. The medical examination must be completed in order for us to process your application.



**U.S. Department of Justice
Immigration and Naturalization Service**

OMB #1115-0134
Medical Examination of Aliens Seeking
Adjustment of Status (P. L. 99-603)

(Please Type or Print Clearly)
I certify that on the date shown I examined:

NAME: LAST	FIRST	MI	DATE OF EXAMINATION MO DA YR	FILE NO.
			DATE OF BIRTH: MO DA YR	COUNTRY OF BIRTH:
ADDRESS: STREET			CITY	STATE ZIP

GENERAL PHYSICAL EXAMINATION

I examined specifically for evidence of the conditions listed below. My examination revealed:

No apparent defect, disease, or disability The conditions listed below were found (check boxes that apply)

CLASS A Conditions			CLASS B Conditions		
<input type="checkbox"/> Chancroid	<input type="checkbox"/> Hansen's Disease, Infectious	<input type="checkbox"/> Tuberculosis, Active	<input type="checkbox"/> Tuberculosis, Not Active		
<input type="checkbox"/> Gonorrhea	<input type="checkbox"/> Lymphogranuloma Venereum	<input type="checkbox"/> Other: _____	<input type="checkbox"/> Hansen's Disease, Not Infectious		
<input type="checkbox"/> Granuloma Inguinale	<input type="checkbox"/> Syphilis, Infectious		<input type="checkbox"/> Other Physical Defect, Disease or Disability		
<input type="checkbox"/> Mental Retardation	<input type="checkbox"/> Previous Occurrence of One or More Attacks of Insanity	<input type="checkbox"/> Mental Defect			
<input type="checkbox"/> Insanity		<input type="checkbox"/> Narcotic Drug Addiction			
<input type="checkbox"/> Sexual Deviation	<input type="checkbox"/> Psychopathic Personality	<input type="checkbox"/> Chronic Alcoholism			

EXAMINATION FOR TUBERCULOSIS**TUBERCULIN SKIN TEST**

FROM Doctor _____
(Please Print)

REACTION mm MO DA YR
 NO REACTION NOT DONE DATE READ

CHEST X-RAY REPORT

FROM Doctor _____
(Please Print)

NORMAL MO DA YR
 ABNORMAL NOT DONE DATE READ

SEROLOGIC TEST FOR SYPHILIS

TEST TYPE _____
 FROM Doctor _____
(Please Print)

REACTIVE TITER MO DA YR
 NONREACTIVE DATE READ

TEST TYPE _____
 FROM Doctor _____
(Please Print)

REACTIVE TITER MO DA YR
 NONREACTIVE DATE READ

IMMUNIZATION DETERMINATION (DTP, OPV, MMR, Td - Refer to PHS Guidelines for recommendations.)

Applicant is current for recommended age-specific immunizations Applicant is not current for recommended age-specific immunizations and I have encouraged that appropriate immunizations be obtained

REMARKS:**CIVIL SURGEON REFERRAL FOR FOLLOW-UP OF MEDICAL CONDITION**

The alien named above has applied for adjustment of status. A medical examination conducted by me identified the conditions above which require resolution before medical clearance is granted or for which the alien may seek medical advice. Please provide follow-up services or refer the alien to an appropriate health care provider. The actions necessary for medical clearance are detailed on the reverse of this form.

FOLLOW-UP INFORMATION

The alien named above has complied with recommended health follow-up.

SIGNATURE

TITLE

MO DA YR

 / /

APPLICANT CERTIFICATION

I certify that the information contained in this form refers to me.

SIGNATURE

MO DA YR

 / /

CIVIL SURGEON CERTIFICATION

My examination showed the applicant to have met the medical examination and health follow-up requirements for adjustment of status.

SIGNATURE

TITLE

MO DA YR

 / /

The Immigration and Naturalization Service is authorized to collect this information under the provisions of the Immigration Reform and Control Act of 1986, Public Law 99-603. The individually identified data requested is required in order for a proper evaluation to be made of your health status, and may be shared with health departments and other public health or cooperating medical authorities. The medical examination must be completed in order for us to process your application.

U.S. Department of Justice
Immigration and Naturalization Service

OMB #1115-0134
Medical Examination of Aliens Seeking
Adjustment of Status (P. L. 99-603)

(Please Type or Print Clearly)
I certify that on the date shown I examined:

NAME: _____	LAST	FIRST	MI	DATE OF EXAMINATION MO DA YR	FILE NO. _____
ADDRESS: _____	STREET			DATE OF BIRTH: MO DA YR	COUNTRY OF BIRTH: _____
				CITY	STATE ZIP

GENERAL PHYSICAL EXAMINATION

I examined specifically for evidence of the conditions listed below. My examination revealed:

No apparent defect, disease, or disability The conditions listed below were found (check boxes that apply)

CLASS A Conditions			CLASS B Conditions		
<input type="checkbox"/> Chancroid	<input type="checkbox"/> Hansen's Disease, Infectious	<input type="checkbox"/> Tuberculosis, Active	<input type="checkbox"/> Tuberculosis, Not Active		
<input type="checkbox"/> Gonorrhea	<input type="checkbox"/> Lymphogranuloma Venereum	<input type="checkbox"/> Other: _____	<input type="checkbox"/> Hansen's Disease, Not Infectious		
<input type="checkbox"/> Granuloma Inguinale	<input type="checkbox"/> Syphilis, Infectious		<input type="checkbox"/> Other Physical Defect, Disease or Disability: _____		
<input type="checkbox"/> Mental Retardation	<input type="checkbox"/> Previous Occurrence of One or More Attacks of Insanity	<input type="checkbox"/> Mental Defect			
<input type="checkbox"/> Insanity		<input type="checkbox"/> Narcotic Drug Addiction			
<input type="checkbox"/> Sexual Deviation	<input type="checkbox"/> Psychopathic Personality	<input type="checkbox"/> Chronic Alcoholism			

EXAMINATION FOR TUBERCULOSIS

TUBERCULIN SKIN TEST

FROM Doctor _____
(Please Print)

 REACTION _____ mm MO DA YR
 NO REACTION NOT DONE DATE READ

CHEST X-RAY REPORT

FROM Doctor _____
(Please Print)

 NORMAL MO DA YR
 ABNORMAL NOT DONE DATE READ

SEROLOGIC TEST FOR SYPHILIS

TEST TYPE _____
FROM Doctor _____
(Please Print)

 REACTIVE TITER MO DA YR
 NONREACTIVE DATE READ

TEST TYPE _____
FROM Doctor _____
(Please Print)

 REACTIVE TITER MO DA YR
 NONREACTIVE DATE READ

IMMUNIZATION DETERMINATION (DTP, OPV, MMR, TD - Refer to PHS Guidelines for recommendations.)

Applicant is current for recommended age-specific immunizations Applicant is not current for recommended age-specific immunizations and I have encouraged that appropriate immunizations be obtained

REMARKS:

CIVIL SURGEON REFERRAL FOR FOLLOW-UP OF MEDICAL CONDITION

The alien named above has applied for adjustment of status. A medical examination conducted by me identified the conditions above which require resolution before medical clearance is granted or for which the alien may seek medical advice. Please provide follow-up services or refer the alien to an appropriate health care provider. The actions necessary for medical clearance are detailed on the reverse of this form.

FOLLOW-UP INFORMATION

The alien named above has complied with recommended health follow-up. _____

SIGNATURE

TITLE

MO DA YR

APPLICANT CERTIFICATION

I certify that the information contained in this form refers to me. _____

SIGNATURE

MO DA YR

CIVIL SURGEON CERTIFICATION

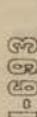
My examination showed the applicant to have met the medical examination and health follow-up requirements for adjustment of status. _____

SIGNATURE

TITLE

MO DA YR

The Immigration and Naturalization Service is authorized to collect this information under the provisions of the Immigration Reform and Control Act of 1986, Public Law 99-603. The individually identified data requested is required in order for a proper evaluation to be made of your health status, and may be shared with health departments and other public health or cooperating medical authorities. The medical examination must be completed in order for us to process your application.



U.S. Department of Justice
Immigration and Naturalization Service

OMB #1115-0134
Medical Examination of Aliens Seeking
Adjustment of Status (P. L. 99 - 603)

(Please Type or Print Clearly)
I certify that on the date shown I examined:

NAME:	LAST	FIRST	MI	DATE OF EXAMINATION MO DA YR	FILE No.	
ADDRESS:				DATE OF BIRTH: MO DA YR	COUNTRY OF BIRTH:	
				CITY	STATE	ZIP

GENERAL PHYSICAL EXAMINATION

I examined specifically for evidence of the conditions listed below. My examination revealed:

 No apparent defect, disease, or disability The conditions listed below were found (check boxes that apply)

CLASS A Conditions			CLASS B Conditions		
<input type="checkbox"/> Chancroid	<input type="checkbox"/> Hansen's Disease, Infectious	<input type="checkbox"/> Tuberculosis, Active	<input type="checkbox"/> Tuberculosis, Not Active		
<input type="checkbox"/> Gonorrhea	<input type="checkbox"/> Lymphogranuloma Venereum	<input type="checkbox"/> Other: _____	<input type="checkbox"/> Hansen's Disease, Not Infectious		
<input type="checkbox"/> Granuloma Inguinale	<input type="checkbox"/> Syphilis, Infectious		<input type="checkbox"/> Other Physical Defect, Disease or Disability: _____		
<input type="checkbox"/> Mental Retardation	<input type="checkbox"/> Previous Occurrence of One or More Attacks of Insanity	<input type="checkbox"/> Mental Defect			
<input type="checkbox"/> Insanity		<input type="checkbox"/> Narcotic Drug Addiction			
<input type="checkbox"/> Sexual Deviation	<input type="checkbox"/> Psychopathic Personality	<input type="checkbox"/> Chronic Alcoholism			

EXAMINATION FOR TUBERCULOSIS**TUBERCULIN SKIN TEST**

FROM Doctor _____

(Please Print)

MO DA YR

 REACTION _____ mm NO REACTION NOT DONE

DATE READ

CHEST X-RAY REPORT

FROM Doctor _____

(Please Print)

MO DA YR

 NORMAL ABNORMAL NOT DONE

DATE READ

SEROLOGIC TEST FOR SYPHILIS**TEST TYPE** _____

FROM Doctor _____

(Please Print)

MO DA YR

 REACTIVE TITER NONREACTIVE

DATE READ

TEST TYPE _____

FROM Doctor _____

(Please Print)

MO DA YR

 REACTIVE TITER NONREACTIVE

DATE READ

IMMUNIZATION DETERMINATION (DTP, OPV, MMR, TD - Refer to PHS Guidelines for recommendations.) Applicant is current for recommended age-specific immunizations Applicant is not current for recommended age-specific immunizations and I have encouraged that appropriate immunizations be obtained**REMARKS:** _____

_____**CIVIL SURGEON REFERRAL FOR FOLLOW-UP OF MEDICAL CONDITION** The alien named above has applied for adjustment of status. A medical examination conducted by me identified the conditions above which require resolution before medical clearance is granted or for which the alien may seek medical advice. Please provide follow-up services or refer the alien to an appropriate health care provider. The actions necessary for medical clearance are detailed on the reverse of this form.**FOLLOW-UP INFORMATION**

SIGNATURE

TITLE

MO DA YR

The alien named above has complied with recommended health follow-up. _____

APPLICANT CERTIFICATION

SIGNATURE

MO DA YR

I certify that the information contained in this form refers to me. _____

CIVIL SURGEON CERTIFICATION

SIGNATURE

TITLE

MO DA YR

My examination showed the applicant to have met the medical examination and health follow-up requirements for adjustment of status. _____

The Immigration and Naturalization Service is authorized to collect this information under the provisions of the Immigration Reform and Control Act of 1986. Public Law 99-603. The individually identified data requested is required in order for a proper evaluation to be made of your health status, and may be shared with health departments and other public health or cooperating medical authorities. The medical examination must be completed in order for us to process your application.



MEDICAL CLEARANCE REQUIREMENTS FOR ALIENS SEEKING ADJUSTMENT OF STATUS

MEDICAL CONDITION	ESTIMATED TIME FOR CLEARANCE	ACTION REQUIRED
Suspected Mental* Conditions	5-30 Days	Applicant must provide to civil surgeon a psychological or psychiatric evaluation from a specialist or medical facility for final classification and clearance.
Tuberculin Skin Test Reaction and Normal Chest X-Ray	Immediate	Applicant should be encouraged to seek further medical evaluation for possible preventive treatment.
Tuberculin Skin Test Reaction and Abnormal Chest X-Ray ("Inactive/Class B")	10-30 Days	Applicant should be referred to physician or local health department for further evaluation. Medical clearance should not be granted until applicant returns to civil surgeon with documentation of medical evaluation for tuberculosis.
Tuberculin Skin Test Reaction and Abnormal Chest X-Ray ("Active or Suspected Active/Class A")	10-300 Days	Applicant should obtain appointment with physician or local health department. If treatment for active disease is started, it must be completed (usually 9 months) before medical clearance granted. At completion of treatment, applicant must present to civil surgeon documentation of completion. If treatment not started, applicant must present to civil surgeon documentation of medical evaluation for tuberculosis.
Hansen's Disease	30-210 Days	Obtain evaluation from specialist or Hansen's disease clinic. If disease is indeterminate or tuberculoid, applicant must present to civil surgeon documentation of medical evaluation. If disease is lepromotous or borderline (dimorphous) and treatment is started, applicant must complete at least 6 months and present documentation to civil surgeon showing adequate supervision, treatment, and clinical response before medical clearance granted.
Venereal Diseases**	1-30 Days	Obtain appointment with physician or local public health department. Applicants with a reactive serologic test for syphilis must provide to civil surgeon documentation of evaluation for treatment. If any of the venereal diseases are infectious, applicants must present to civil surgeon documentation of completion of treatment.
Immunizations Incomplete	Immediate	Applicant should be encouraged to go to physician or local health department for appropriate immunizations.

*Mental retardation; insanity, previous attack of insanity, psychopathic personality, sexual deviation, or mental defect, narcotic drug addiction, and chronic alcoholism.

**Chancroid, gonorrhea; granuloma inguinale, lymphogranuloma venereum, and syphilis.

Application for Waiver of Grounds of Excludability
Under Sections 245A or 210 of the Immigration and Nationality Act

I-690 Instructions

Please carefully read all of the instructions.

The fee will not be refunded.

1. Filing the Application

The application and supporting documentation should be taken or mailed to an American Consulate if the applicant is outside of the United States and is applying for temporary resident status as a Special Agricultural Worker.

If the applicant is in the United States, a participating Qualified Designated Entity near your place of residence, or

The Service legalization office having jurisdiction over the applicant's place of residence or employment.

2. Fee

A fee of thirty-five dollars (\$35.00), is required at the time of filing. The fee is not refundable regardless of the action taken on the application.

A separate cashier's check or money order must be submitted for each application. *All fees must be submitted in the exact amount.* The fee must be in the form of a cashier's check or money order. No cash or personal checks will be accepted. The cashier's check or money order must be made payable to "Immigration and Naturalization Service" unless applicant resides in the Virgin Islands or Guam. (Applicants residing in the Virgin Islands make cashier's check or money order payable to "Commissioner of Finance of the Virgin Islands." Applicants residing in Guam make cashier's check or money order payable to "Treasurer, Guam."

A fee is not required if this application is filed for an alien who:

- Is afflicted with tuberculosis;
- Is mentally retarded; or
- Has a history of mental illness.

3. Applicants with Tuberculosis.

An applicant with active tuberculosis or suspected tuberculosis must complete Statement A on page two of this form. The applicant and his or her sponsor is also responsible for having:

Statement B completed by the physician or health facility which has agreed to provide treatment or observation, and

Statement C, if required, completed by the appropriate local or state health officer.

This form should then be returned to the applicant for presentation to the consular office, or to the appropriate office of the Immigration and Naturalization Service.

Submission of the application without the required fully executed statements will result in the return of the application to the applicant without further action.

4. Applicants with Mental Conditions.

An alien who is mentally retarded or who has a history of mental illness shall attach a statement that arrangements have been made for the submission of a medical report, as follows, to the office where this form is filed:

The medical report shall contain:

A complete medical history of the alien, including details of any hospitalization or institutional care or treatment for any physical or mental condition;

Findings as to the current physical condition of the alien, including reports of chest X-rays and a serologic test if the alien is 15 years of age or older, and other pertinent diagnostic tests; and

Findings as to the current mental condition of the alien, with information as to prognosis and life expectancy and with a report of a psychiatric examination conducted by a psychiatrist who shall, in case of mental retardation, also provide an evaluation of intelligence.

For an alien with a past history of mental illness, the medical report shall also contain available information on which the United States Public Health Service can base a finding as to whether the alien has been free of such mental illness for a period of time sufficient in the light of such history to demonstrate recovery.

The medical report will be referred to the United States Public Health Service for review and, if found acceptable, the alien will be required to submit such additional assurances as the United States Public Health Service may deem necessary in his or her particular case.

U.S. Department of Justice
Immigration and Naturalization Service

OMB #1115-0132

Please begin with item #1, after carefully reading the instructions.

The block below is for Government Use Only

Name and Location (City or Town) of Qualified Designated Entity	Fee Stamp
	Fee Receipt No. (This application)
Qualified Designated Entity I.D. No.	File No. (This applicant) A

Applicant: Do not write above this line. See instructions before filling in application. If you need more space to answer fully any question on this form, use a separate sheet and identify each answer with the number of the corresponding question. Fill in with typewriter or print in block letters in ink.

I&NS USE ONLY

Recommended by:

(Print or Type Name and Title)

Date

Signature

Signature _____

Form I-690 (02/14/87)

104

Director, Regional Processing Facility

A. APPLICANT

Instructions: Leave this side blank if your Application for Waiver of Grounds of Excludability is for any reason other than active or suspected tuberculosis. If your application is due to active or suspected tuberculosis, take this form to any physician or medical facility under contract with the Immigration and Naturalization Service. Have the physician complete Section B. You must sign Section A (below) *in the presence of the physician*.

If medical care will be provided by a physician who checked Box 3 or 4 in Section B, have Section C completed by the local or State Health Officer who has jurisdiction in the area where you reside. Present the form to the Health Officer after Sections A and B on this side, and all sections on the other side have been completed.

Statement: I have reported to the physician or health facility named in Section B; have presented all X-Rays used in the Legalization medical examination to substantiate diagnosis; will submit to such examinations, treatment, isolation, and medical regimen as may be required; and will remain under the prescribed treatment or observation whether on inpatient or outpatient basis, until discharged at the discretion of the physician named, or a physician representing the facility named in Section B. Satisfactory financial arrangements have been made. (NOTE: This statement does not relieve you from submitting evidence to establish that you are not likely to become a public charge.)

A. Signature of Applicant	Date
---------------------------	------

B. PHYSICIAN OR HEALTH FACILITY

Instructions: This section of Form I-690 may be executed by a physician in private practice (under contract with the Immigration and Naturalization Service), or a physician employed by a health department, other public health facility, or military hospital.

Complete Section B (below) of this form, and have alien sign and date Section A (above) *in your presence. Please be sure the alien's signature above, and the alien's signature on the other side of this form are identical.*

Statement: I agree to supply any treatment or observation necessary for the proper management of the alien's tuberculous condition. I agree to submit Form CDC 75.18 to the health officer named below (*Section C) within thirty (30) days of the alien's reporting for care, indicating presumptive diagnosis, test results, and plans for future care of the alien. Satisfactory financial arrangements have been made.

I represent (enter X in the appropriate box and type or legibly print name and address of facility):

1. Local Health Department
2. Military Hospital
3. Other Public Health Facility
4. Private Practice or Private Health Facility under contract with the Immigration and Naturalization Service.

B. Signature of Physician	Date
---------------------------	------

Print or Type Name and Address of Physician and Facility. (If military, enter name and address of receiving hospital and mail directly to Centers for Disease Control, Atlanta, GA 30333.)

C. LOCAL OR STATE HEALTH OFFICER

Instructions: If the facility or physician who signed in Section B is not in your health jurisdiction and is not familiar to you, you may wish to contact the health officer responsible for the jurisdiction of the facility or physician prior to endorsing this document.

Statement: This endorsement signifies recognition of the physician or facility for the purpose of providing care for tuberculosis.

C. Signature of Health Officer	Date
--------------------------------	------

Print or Type Name of Health Officer*, and Official Name and Complete Address of Local Health Department.

INSTRUCTIONS

Form I-694

1. FILING AN APPEAL:

This form must be mailed to the address given on the "Notice of Denial", and must be received within 30 days of the date on that notice. No extensions will be granted.

2. BRIEFS:

A brief in support of an appeal is not required, but may be desired. If a brief is to be submitted, it must be submitted with this appeal form. No extensions will be granted.

ORAL ARGUMENT:

Oral argument before the Commissioner or an officer designated by him may be requested by letter attached to this notice. The letter must set forth the reasons oral argument is desired in support of or in place of a brief. Oral argument will be denied in any case where the appeal is found to be frivolous, where oral argument will serve no useful purpose or where written material or representations will appropriately serve the interests of the appellant. If oral argument is granted, it must be held in person. The officer to whom the appeal is taken will designate in writing the time, date, and place of the oral argument. Oral argument in any one case will be limited to fifteen (15) minutes, unless justification and arrangements for additional time are made in advance.

3. COUNSEL:

In presenting and prosecuting this appeal the appellant may, if he or she desires, be represented at no expense to the Government by counsel or other duly authorized representatives.

4. FEE:

A fee of fifty dollars (\$50.) must be paid for filing this appeal. It cannot be refunded regardless of the action taken on the appeal. A separate cashier's check or money order must be submitted for each application. *All fees must be submitted in the exact amount.* The fee must be in the form of a cashier's check or money order. No cash or personal checks will be accepted. The cashier's check or money order must be payable to "Immigration and Naturalization Service" unless the appellant resides in the Virgin Islands or Guam. (Appellants residing in the Virgin Islands make cashier's check or money order payable to "Commissioner of Finance of the Virgin Islands". Appellants residing in Guam make cashier's checks or money orders payable to "Treasurer, Guam".)

U.S. Department of Justice
Immigration and Naturalization Service

Notice of Appeal of Decision under
Section 210 or 245A of the Immigration and Nationality Act.

OMB #1115-0135

In the Matter of:	FEE STAMP	
Application for: <input type="checkbox"/> Permanent Residence <input type="checkbox"/> Temporary Residence <input type="checkbox"/> Waiver of Grounds of Excludability	File No.: A -	
I hereby appeal to the Commissioner from the decision, dated _____ in the above entitled case.		
<input type="checkbox"/> My written brief or statement is attached. <input type="checkbox"/> I waive the right to submit a written brief or statement.		
Briefly, state reasons for this appeal.		
APPELLANT (OR ATTORNEY OR REPRESENTATIVE) Please complete the following.		
Name (Type or Print)		
Address (Street Name and Number)		
(City or Town)	(State)	(ZIP Code)
Title or Relationship to Appellant, if other than appellant.		
Signature X	Date	

PLACE
POSTAGE
STAMP
HERE

Immigration and Naturalization Service

Change of Address Card for Legalization
and Special Agricultural Workers

*This card is NOT to be used by persons other than those applying for
legal status under Sec. 245A or Sec. 210 of P.L. 99-603.*

Change of Address Card for Legalization and Special Agricultural Workers
*This card is NOT to be used by persons other than those applying for
legal status under Sec. 245A or Sec. 210 of P.L. 99-603.*

U.S. Department of Justice
Immigration and Naturalization Service

Change of Address Card for Legalization
and Special Agricultural Workers (SAW)

OMB #1115-0130

INSTRUCTIONS: This form is to be used ONLY by Legalization and SAW applicants (in connection with an application for status under Sec. 245A or Sec. 210 of the Immigration and Nationality Act) reporting a change of address. Mail to the Legalization Office where your application was submitted.

Name (Last in CAPS)	(First)	(Middle)
Country of Birth	Date of Birth (Month/Day/Year)	A-File No:
Present Address (Street or Rural Route)	(City or Post Office)	(State and ZIP Code)
IF ABOVE ADDRESS IS TEMPORARY I expect to remain there _____ years _____ months		
Last Address (Street or Rural Route)	(City or Post Office)	(State and ZIP Code)
SIGNATURE	DATE	

Form I-697 (02-14-87)

INSTRUCTIONS Form I-695

COMPLETE APPLICATION

Items 1-11

Type or print in block letters, in ink, all information requested in items 1 through 11.

Item 12. Explanation.

Type or print in block letters, in ink, the reason a new document is needed. If information on the original was incorrect when it was issued, or has since changed, provide that information as it appears on the original. If the original has been destroyed, lost, or stolen, explain how you believe that happened and provide the date (or approximate date) you believe the incident occurred. If the space provided in block 12 is not adequate, attach an additional sheet.

Item 13.

Applicant must sign and date item 13.

Item 14.

If the person preparing this form is other than the applicant, that person must sign and date item 14.

SUBMIT ALL of the following, *IN PERSON*, with this application to the Immigration Legalization Office having jurisdiction over your place of residence:

DOCUMENT, if the document previously issued to you was mutilated.

CASHIER'S CHECK OR MONEY ORDER, in the amount of \$15.00, made payable to the "U.S. Immigration and Naturalization Service." This fee is for filing the application and **MAY NOT BE REFUNDED**. (Applicants residing in the Virgin Islands make cashier's check or money order payable to "Commissioner of Finance of the Virgin Islands." Applicants residing in Guam make cashier's check or money order payable to "Treasurer, Guam.")

PHOTOGRAPHS (2), taken within 30 days of the date of this application. Photographs must have a white background, be glossy, unretouched, and not mounted; dimension of facial image should be about one inch from chin to top of hair, and should be $\frac{3}{4}$ frontal view showing right side of face with right ear visible. Use pencil or felt pen to lightly print your name on the back of **EACH** photograph, **AS IT IS TO APPEAR ON THE REPLACEMENT DOCUMENT**.

PENALTIES: Severe penalties are provided by law for knowingly and willfully falsifying or concealing a material fact or using any false document in the submission of this application. Also, a false representation may result in the denial of this application and any other application you may make for any benefit under the immigration laws of the United States.

U.S. Department of Justice
Immigration and Naturalization Service

OMB #1115-0129
Application for Replacement of Form I-688A, Employment Authorization,
or Form I-688, Temporary Residence Card (Under P.L. 99-603)

Please begin with item #1, after carefully reading the instructions.

The block below is for Government Use Only.

Name and Location (City or Town) of Qualified Designated Entity	Fee Stamp
	Fee Receipt No. (This application)
Qualified Designated Entity I.D. No.	File No. (This applicant) A -

Please read instructions on reverse.
FEE WILL NOT BE REFUNDED.

1. I hereby apply for a replacement of <input type="checkbox"/> Form I-688A, Employment Authorization Card <input type="checkbox"/> Form I-688, Temporary Residence Card	A replacement is needed because: <input type="checkbox"/> Original was lost, stolen, or destroyed. (Give date and details in Block 12.) <i>(If reason is one of the following, attach original document.)</i> <input type="checkbox"/> Original was incorrect when issued (no fee required) <input type="checkbox"/> Original was mutilated		
2. Family Name (Last Name in CAPITAL Letters) (First Name) (Middle Name)	3. Date of Birth (Month/Day/Year)		
4. Home Address in the U.S. (No. and Street) (Apt. No.)	(City)	(State)	(ZIP Code)
5. Telephone Numbers (Include Area Code) Home: Work:	6. Name used when admitted as temporary resident (If different from #2):		
7. The date you were admitted or adjusted to temporary residence status:	8. Social Security Number:		
9. Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female	10. Place of Birth: (Town/City) (State/Country)	11. Country of Citizenship:	
12. Explanation:			
13. Signature of Applicant: I CERTIFY that the information above is true and correct to the best of my knowledge and belief. If original document is not attached, I agree to mail it to the Legalization office in the event it is recovered.		Signature _____ Date Signed _____	
14. Signature of Person Preparing Form if other than applicant: I DECLARE that this application was prepared by me at the request of the applicant and is based on all information of which I have any knowledge.			
Signature _____ Address _____ Date Signed _____			
This section for use by IMMIGRATION OFFICER only. Recommend Application be: <input type="checkbox"/> Granted <input type="checkbox"/> Denied By: _____ (Immigration Officer) (Date)			
Director, Regional Processing Facility:	Replacement Issued by:	On (Date):	Replacement Receipt No.:

Employment Eligibility Verification

NOTICE: Authority for collecting the information on this form is in Title 8, United States Code, Section 1324A. It will be used to verify the individual's eligibility for employment in the United States. Failure to present this form for inspection to officers of the Immigration and Nationality Service or Department of Labor within the time period specified by regulation, or improper completion or retention of this form may be a violation of 8 USC §1324A and may result in a civil money penalty.

Section 1. Employee's/Preparer's instructions for completing this form.

Instructions for the employee.

All employees, upon being hired, must complete Section 1 of this form. Any person hired after November 6, 1986 must complete this form. (For the purpose of completion of this form the term "hired" applies to those employed, recruited or referred for a fee.)

All employees must print or type their complete name, address, date of birth, and Social Security Number. The block which correctly indicates the employee's immigration status must be checked. If the second block is checked, the employee's Alien Registration Number must be provided. If the third block is checked, the employee's Alien Registration Number **or** Admission Number must be provided, as well as the date of expiration of that status, if it expires.

All employees must sign and date the form.

Instructions for the preparer of the form, if not the employee.

If the employee is assisted with completing this form, the person assisting must certify the form by signing it, and printing or typing their complete name and address.

Section 2. Employer's instructions for completing this form.

(For the purpose of completion of this form, the term "employer" applies to employers and those who recruit or refer for a fee.)

Employers must complete this section by examining evidence of identity and employment authorization, and:

- checking the appropriate box in List A **or** boxes in both Lists B and C;
- recording the document identification number and expiration date (if any);
- recording the type of form if not specifically identified in the list;
- signing the certification section.

NOTE: Employers are responsible for reverifying employment eligibility of aliens upon expiration of any employment authorization documents, should they desire to continue the alien's employment.

Copies of documentation presented by an individual for the purpose of establishing identity and employment eligibility may be copied and retained for the purpose of complying with the requirements of this form and no other purpose. Any copies of documentation made for this purpose should be maintained with this form.

Employers may photocopy or reprint this form, as necessary, for their use.

RETENTION OF RECORDS.

After completion of this form, it must be retained by the employer during the period beginning on the date of hiring and ending:

- three years after the date of such hiring, or;
- one year after the date the individual's employment is terminated, whichever is later.

EMPLOYMENT ELIGIBILITY VERIFICATION

1 EMPLOYEE INFORMATION AND VERIFICATION: (To be completed and signed by employee.)

Name: (Print or Type) Last	First	Middle	Maiden
Address: Street Name and Number	City	State	ZIP Code
Date of Birth (Month/Day/Year)	Social Security Number		

I attest, under penalty of perjury, that I am (check a box):

- A citizen or national of the United States.
 An alien lawfully admitted for permanent residence. (Alien Number A _____).
 An alien authorized by the Immigration and Naturalization Service to work in the United States. (Alien Number A _____).
 or Admission Number _____, expiration of employment authorization, if any _____).

I attest, under penalty of perjury, the documents that I have presented as evidence of identity and employment eligibility are genuine and relate to me. I am aware that federal law provides for imprisonment and/or fine for any false statements or use of false documents in connection with this certificate.

Signature _____ Date (Month/Day/Year) _____

PREPARER/TRANSLATOR CERTIFICATION (If prepared by other than the individual). I attest, under penalty of perjury, that the above was prepared by me at the request of the named individual and is based on all information of which I have any knowledge.

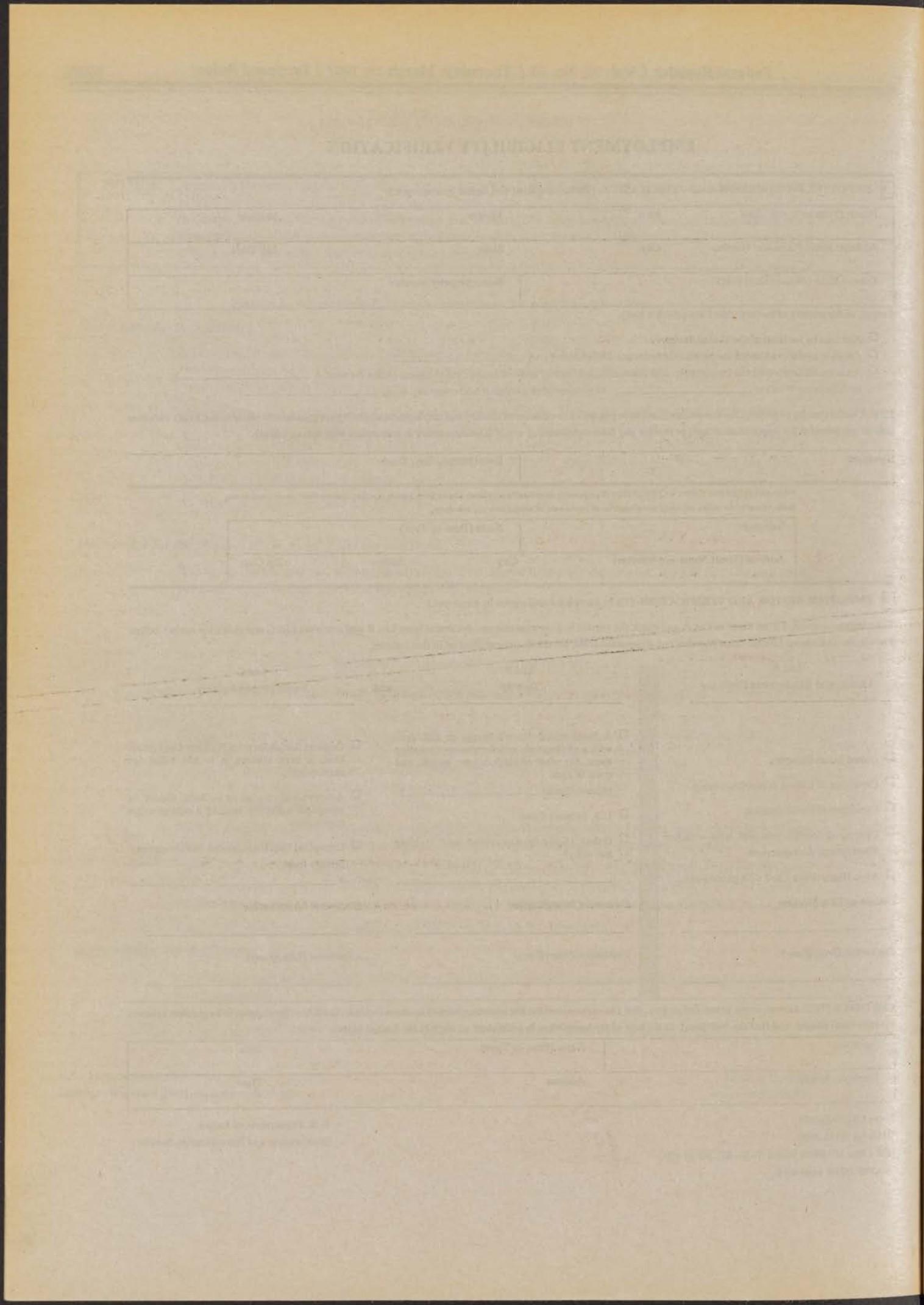
Signature	Name (Print or Type)		
Address (Street Name and Number)	City	State	Zip Code

2 EMPLOYER REVIEW AND VERIFICATION: (To be completed and signed by employer.)Examine one document from those in List A and check the correct box, or examine one document from List B and one from List C and check the correct boxes. Provide the *Document Identification Number* and *Expiration Date*, for the document checked in that column.

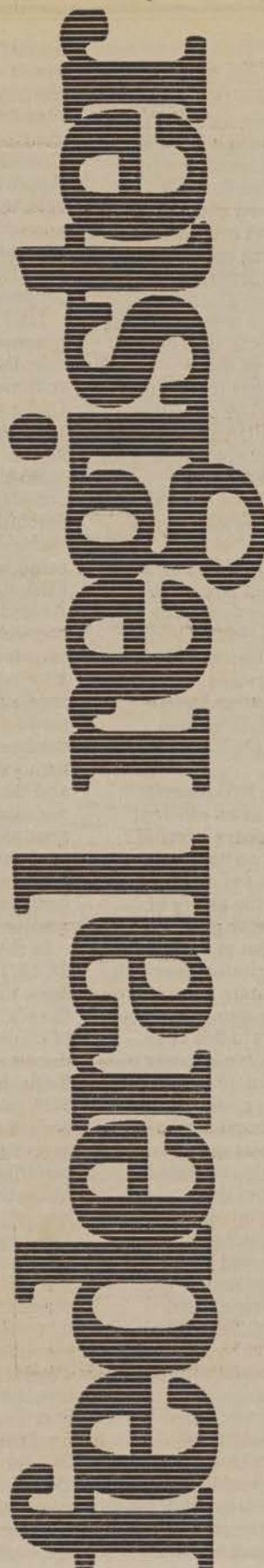
List A Identity and Employment Eligibility	List B Identity and	List C Employment Eligibility
<input type="checkbox"/> United States Passport <input type="checkbox"/> Certificate of United States Citizenship <input type="checkbox"/> Certificate of Naturalization <input type="checkbox"/> Unexpired foreign passport with attached Employment Authorization <input type="checkbox"/> Alien Registration Card with photograph <i>Document Identification</i> # _____ <i>Expiration Date (if any)</i> _____	<input type="checkbox"/> A State issued driver's license or I.D. card with a photograph, or information, including name, sex, date of birth, height, weight, and color of eyes. (Specify State) _____ <input type="checkbox"/> U.S. Military Card <input type="checkbox"/> Other (Specify document and issuing authority) _____ <i>Document Identification</i> # _____ <i>Expiration Date (if any)</i> _____	<input type="checkbox"/> Original Social Security Number Card (other than a card stating it is not valid for employment) <input type="checkbox"/> A birth certificate issued by State, county, or municipal authority bearing a seal or other certification <input type="checkbox"/> Unexpired INS Employment Authorization Specify form # _____ <i>Document Identification</i> # _____ <i>Expiration Date (if any)</i> _____

CERTIFICATION: I attest, under penalty of perjury, that I have examined the documents presented by the above individual, that they appear to be genuine, relate to the individual named, and that the individual, to the best of my knowledge, is authorized to work in the United States.

Signature	Name (Print or Type),	Title
Employer Name	Address	Date



Thursday
March 19, 1987



Part VII

**Department of
Health and Human
Services**

Food and Drug Administration

**21 CFR Parts 312, 314, 511, and 514
New Drug, Antibiotic, and Biologic, Drug
Product Regulations; Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 312, 314, 511, and 514**

[Docket No. 82N-0394]

New Drug, Antibiotic, and Biologic Drug Product Regulations**AGENCY:** Food and Drug Administration.**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its regulations governing the submission and review of investigational new drug applications (IND's). The new regulations (called the IND Rewrite) will ensure FDA's ability to monitor carefully the safety of patients participating in clinical investigations, while also facilitating the development of new beneficial drug therapies. The improvements will also help sponsors of clinical investigations prepare and submit high quality IND applications and permit FDA to review them efficiently and with minimal delay. This action is one part of a larger effort by FDA to improve the agency's drug approval process, including the earlier publication of companion regulations governing new drug applications (NDA's) for marketing approval.

Elsewhere in this issue of the *Federal Register*, FDA is reproposing procedures governing: (1) Availability of investigational drugs for treatment use; and (2) sale of investigational drugs. Both of these issues had been addressed in the IND Rewrite proposal.

DATES: These final regulations are effective June 17, 1987. FDA will, however, accept applications until March 19, 1988, that are in the format required under either the current regulations or this final rule. For additional information concerning this effective date, see "Paperwork Reduction Act" appearing in the preamble of this document. Comments regarding "Outside Review Boards" by April 20, 1987.

ADDRESS: Written comments on the revised regulations to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Steven H. Unger, Center for Drugs and Biologics (HFN-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8046.

SUPPLEMENTARY INFORMATION:

I. Introduction

This final rule continues the rulemaking efforts by the Department of Health and Human Services and FDA to revise Federal regulations governing the new drug approval process. This phase of the regulations (called the IND Rewrite) makes final new procedures in 21 CFR Part 312 for FDA review of investigational new drug applications and for monitoring the progress of investigational drug use. The IND Rewrite was issued as a proposal in the *Federal Register* of June 9, 1983 (48 FR 26720). The first phase of these regulatory revision efforts (called the NDA Rewrite) covers FDA procedures in 21 CFR Part 314 for FDA review of new drug and antibiotic applications for marketing. This first phase was completed with publication of final regulations in the *Federal Register* of February 22, 1985 (50 FR 7452). Collectively, the IND and NDA Rewrites conclude an effort begun when FDA made concept papers available for public comment (44 FR 58919; October 12, 1979) and held a public meeting on November 9, 1979, to discuss them. These regulations are promulgated under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 et seq.).

The objectives of the IND Rewrite final rule are to establish an efficient investigational drug process in order both: (a) To focus FDA's attention during the early phase of clinical research on protecting the safety of human test subjects and to give sponsors greater freedom to design, revise, and implement clinical research studies; and (b) to facilitate consultation between FDA and drug sponsors, once the preliminary human studies have been completed and a drug appears to have marketing potential, to help ensure that the design of major clinical trials is acceptable and will support marketing approval if the test results are favorable. These regulations are also intended to encourage innovation and drug development while continuing to assure the safety of test subjects. In addition, through better planning and closer consultation, FDA's later review of applications for marketing should proceed more efficiently. These changes will benefit the consumer by enhancing the prompt marketing availability of safe and effective therapies.

In preparing the final rule, FDA carefully reviewed more than 50 comments received from pharmaceutical manufacturers, trade associations, health professionals, professional societies, and consumer organizations. In addition, FDA managers met with

agency employees in order to gain their views as part of the internal decisionmaking process. The agency also considered the recommendations of the Congressionally sponsored Commission on the Federal Drug Approval Process. In preparing the final rule, therefore, the agency has considered views of persons representing virtually all groups having an interest in the investigational drug process.

Like the IND and NDA Rewrite proposals and the NDA Rewrite final rule, the IND final rule has been reviewed in accordance with Executive Order 12291 (46 FR 13193; February 19, 1981) and the policy objectives outlined above.

FDA's IND Rewrite final rule complements the revised NDA regulations. For example, one of the themes of the IND/NDA Rewrites is to establish a continuing dialogue between FDA staff and drug sponsors/applicants. Accordingly, the regulations codify a sequence of four standard conferences targeted at key stages of the drug approval process. These are (in the IND regulations) the "end-of-Phase 2 conference" and the "pre-NDA conference" and (in the NDA regulations) the "ninety-day conference" and the "end-of-review conference." In addition, both the IND and NDA regulations provide for other communication between FDA staff and sponsors/applicants on an as needed basis, as well as a strong commitment to resolve any disputes in a timely manner.

In the *Federal Register* of September 27, 1977 (42 FR 49612), FDA proposed to issue rules (21 CFR Part 52) governing the obligations of sponsors and monitors of clinical investigations. In related document, published in the *Federal Register* of August 8, 1978 (43 FR 35210), FDA proposed comprehensive rules governing the obligations of clinical investigators (21 CFR Part 54). While restating and clarifying many of the obligations of sponsors and clinical investigators previously set forth in the IND regulations (§ 312.1), these two documents also proposed to: (a) Change some existing requirements covering the conduct and review of clinical investigations; and (b) extend the requirements to persons who conduct clinical investigations of any product regulated by FDA. On the assumption that these two proposals would be made final before, or at the same time as, the IND Rewrite final rule, the agency in the IND Rewrite proposal did not systematically address issues relating to sponsor and clinical investigator responsibilities.

Because those proposals to establish Parts 52 and 54 have not been made final, FDA has retained in new Part 312 most of those existing requirements governing clinical investigator and sponsor/monitor obligations that were to have been transferred to proposed Parts 52 and 54. The responsibilities of sponsors and clinical investigators prescribed in this final rule are substantially the same as those set forth in the existing IND regulations.

In connection with issuance of the IND and NDA Rewrites, FDA has significantly expanded the use of guidelines. FDA has recently issued guidelines on how to fulfill certain technical requirements in order to provide applicants with greater guidance in these areas. These guidelines, which apply to regulatory requirements for both NDA and IND applications, should materially assist implementation of the new regulations.

Elsewhere in this issue of the *Federal Register*, FDA is reproposing new rules on: (i) The distribution of drugs for treatment use and (ii) the sale of investigational drugs. Comments received on these issues are addressed in the reproposal. Pending the adoption of new rules on the sale of investigational drugs, FDA has retained in this final rule the current provisions on sale.

Highlights of the final IND rule, the agency's economic analysis, and a discussion of related issues are contained in the following introductory sections. The remainder of this preamble is devoted to a section-by-section analysis of comments received, responses to them, and the contents of the final regulations.

II. Highlights of the Final Rule

The guiding principle in the IND Rewrite final rule is that different stages of the IND process will be regulated differently. Safety concerns will predominate at the beginning of the process to ensure that research subjects are not exposed to unreasonable risks. In the later phases of drug investigation, FDA will also evaluate the scientific merit of study protocols to ensure that planned clinical studies are capable of producing valid information on safety and effectiveness necessary to obtain marketing approval. In response to comments and further internal deliberations, the final rule has modified certain provisions of the proposal to meet these objectives better. The major provisions of the final rule are summarized as follows:

1. *Regulation of the early phase of human research.* The final rule incorporates the proposed revisions

designed to give drug sponsors greater freedom during the early phase of human research (Phase 1) by permitting such research to proceed unless it presents an unreasonable and significant risk to test subjects. Thus, the final rule narrows the scope of FDA's review of Phase 1 studies to focus on the safety of human test subjects and permit clinical investigators in Phase 1 to modify protocols on the basis of experience gained during the investigation without prior notification to FDA. Moreover, the final rule emphasizes to drug sponsors that the amount of toxicology and chemistry information required in the initial IND submission depends on the nature and extent of the proposed clinical studies. These changes are intended to encourage innovation in drug development while continuing current safeguards governing the safety of test subjects.

In the proposed rule, FDA solicited comments on the merits of adopting a dual track system for Phase 1 studies in which drug firms would have the option of submitting IND's either to FDA or to nongovernmental "Outside Review Boards" (ORB's). As discussed later in this preamble, FDA has decided to solicit further comment on the feasibility of ORB's, focusing in particular on the possible establishment of a pilot program.

2. *Format for IND submission.* The final rule establishes a new format for IND submissions, similar to that in the proposal, that will result in better organized applications and thus facilitate agency review. The revised format focuses on the proposed human studies so that supporting toxicology and chemistry information can be reviewed in light of the proposed clinical investigations. The new IND will consist of a greatly simplified IND form that serves as a cover sheet, a brief overview of the investigational plan, and the protocols and supporting technical information on the drug's chemistry, pharmacology, and toxicology.

3. *IND safety reports.* The final rule specifies a drug company's obligations in reviewing and reporting adverse drug reaction information, clarifying the proposal in several respects. The rule requires that sponsors promptly review and evaluate all safety information received by the sponsor and that the sponsor report to FDA within 10 working days all adverse drug reactions that are both serious and unexpected. In addition, the final rule requires the sponsor to notify FDA by telephone of any unexpected death or life-threatening experience no later than 3 working days

after the sponsor first learns of the experience. This telephone call will provide an early warning of the most serious kinds of adverse experiences and will enable FDA to discuss with the sponsor the need, if any, to modify or discontinue the study. These safety report provisions should significantly improve FDA's ability to monitor the safety of clinical studies.

4. *Amendment procedures.* Like the proposal, the final rule divides the IND amendment procedures into three distinct categories: (i) Protocol amendments, for new protocols and changes in existing protocols; (ii) information amendments, for additional data as they develop; and (iii) IND safety reports, as described above. Appropriate reporting intervals apply to each category depending upon the need for prompt agency review. The final rule also clarifies the scope of the annual reports, which are intended to provide an overview of the progress to date and future plans for the IND.

5. *Meetings between FDA and drug sponsors.* The final rule codifies FDA's proposal to extend to the sponsor of any IND an opportunity for an "end-of-Phase 2" conference with FDA to obtain concurrence on an overall plan for the conduct of Phase 3 trials and the design of specific studies. The final rule also codifies the policy that gives IND sponsors and opportunity to meet with FDA for a "pre-NDA" conference to discuss appropriate formats for data presentation in a marketing application.

6. *"Clinical hold" procedures.* The final rule adopts procedures essentially the same as those contained in the proposal pertaining to FDA's instituting a "clinical hold." A clinical hold is an order either not to begin or not to continue a clinical study. The final rule limits clinical holds in Phase 1 studies to situations where there is an unreasonable and significant risk to human subjects. In Phases 2 and 3, FDA's authority to issue a clinical hold would extend to serious defects in study design that would render the study incapable of producing valid evidence of safety and effectiveness. All clinical holds must be approved by the director of the division in FDA's Center for Drugs and Biologics with responsibility for review of the IND.

7. *Exemptions for certain studies on marketed drugs.* The final rule exempts from most IND requirements certain investigations conducted with drugs already approved for marketing. The exemption applies where safety is not an issue (because of a similarity in dose route of administration, and patient population with the approved labeling)

and where the investigation is not being conducted for the purpose of changing the drug labeling (for example, where the study is not for purposes of adding a new indication or comparative safety claim). The agency expects that this exemption will apply primarily to researchers in academic or other institutions. This exemption is intended to reduce burdens on researchers while permitting FDA resources to be devoted to monitoring clinical investigations requiring FDA oversight and to reviewing marketing applications. Although exempt from most IND requirements, the investigations would nonetheless be subject to the general prohibition against promotion of investigational drugs (§ 312.7), and to the other regulations designed to protect the rights and safety of patients, such as the institutional review board (21 CFR Part 56) and informed consent (21 CFR Part 50) regulations.

8. Dispute resolution. The final rule has been significantly revised to emphasize, similar to the NDA final rule, the use of informal meetings and other informal communications as the means for resolving differences between FDA and sponsors. For administrative and procedural issues, the final rule establishes an ombudsman whose function will be to facilitate timely and equitable resolutions of administrative and managerial disagreements about IND's. For scientific and medical disputes, the final rule encourages applicants to seek resolution through informal meetings with appropriate agency staff and management representatives as the need may arise. The final rule also provides for the participation of outside experts at these informal meetings when feasible. This procedure supersedes the appeals process described in the IND Rewrite proposal.

III. Economic Analysis

FDA has examined the economic consequences of the changes implemented by the final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354). The agency concludes that these revisions will have favorable economic impacts on the health care system, drug sponsors, and the agency without compromising the safety of human subjects. Although some of these favorable impacts are quantifiable, others with greater potential for savings can only be characterized in a very generalized, nonquantitative manner at this time.

Quantifiable impacts include an estimated net annual savings of \$4.9 million to sponsors, arising from a

simplified IND format; reduced and/or staged submission of manufacturing and controls data; a reduction in the number of amendments that are submitted during the first year that an IND is active; savings in start-up expenses associated with studies that would no longer be placed on clinical hold under the revised criteria; and savings of sponsor-investigator resources currently used to prepare IND's that will no longer be necessary. The only projected cost increase is modest by comparison and arises from requirements to improve the quality of annual reports. These revisions will also produce some savings in agency review resources.

A potential for substantially larger savings is presented by the provisions for increased use of guidelines, meetings, and informal advice to aid commercial IND sponsors in assembling the data for those IND's that lead to the submission of a marketing application. These initiatives, taken together, could result in substantial savings from fewer deficiencies being noted in the NDA review process due to better designed clinical trials, as well as further savings from the elimination of some unnecessary or poorly designed clinical studies. For example, gaining advice on the proper protocol for a major clinical study could save a year or more in the process if it prevents the need to redo certain key research as a result of faulty study design.

As stated in the proposal, the agency concludes that these revisions are not a major rule as defined in Executive Order 12291. The agency also certifies that the changes will not have a significant impact on a substantial number of small entities. The net savings, described above, will accrue to all sponsors, regardless of size, and the preponderance of unquantifiable savings will probably accrue to the public and to sponsors of commercial IND's, most of whom are not small entities. A copy of the agency's revised assessment of economic impact is on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

The revisions to the IND regulations have a significance well beyond the specific cost reductions summarized above. As noted earlier, these regulations are part of a comprehensive review of the new drug approval process designed to accelerate the development and marketing of new drug therapies without compromising the safety and effectiveness of new drugs. Collectively, FDA's new regulations, guidelines, procedures, and policies should produce

considerable benefits. A quicker, more efficient drug development process means that the American public will have more safe and effective drugs sooner. A less costly drug development process means that the pharmaceutical industry will be able to develop more new drugs with the same number of research dollars, or alternatively to market less costly drugs. Either outcome will be of direct benefit to the American public. Most importantly, the prompt availability of safe and effective drug therapies has enormous potential benefit to patients and the public in terms of improving the length and quality of life and in reducing health care and hospital costs.

IV. Paperwork Reduction Act of 1980

This final rule contains information collection requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3507 of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910-0162.

Only § 312.33 contains changes that are different from the proposal that was submitted to OMB that may require a change in the reporting burden. Revised information collection estimates reflecting these changes will be submitted for approval to OMB. The reporting requirements of § 312.33 will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the *Federal Register* prior to June 17, 1987.

V. Comments on the Proposed Rule

Applicability of IND Requirements (§ 312.2)

1. Changes permitted to marketed product. Many comments asked for clarification of the proposed exemption in § 312.2. The exemption would permit a sponsor to conduct a study with a lawfully marketed drug without having to submit an IND if the study did not involve use of the drug in a way that significantly increased the risks associated with use of the product, and if certain other conditions were met. These comments in general were interested in knowing to what extent a sponsor could change the drug product or the conditions of the drug's use and remain within the terms of the exemption. Specifically, one comment asked whether it would be permissible to conduct a study with a capsule of a drug that is lawfully marketed in tablet

form. Other comments urged that the exemption permit modifications in the packaging or labeling of a marketed drug that do not affect a product's quality, safety, or effectiveness.

The exemption was not intended to require an investigator to use the drug in exactly the dosage form, dosage levels, and patient populations described in the marketed labeling for the product, but rather to permit changes to the lawfully marketed drug product that do not increase the risks (or, as explained in response to paragraph 8 below, the acceptability of the risks) over the risk presented by use of the product in conformance with its marketed labeling. Because assessing the risks involved in specific uses of a product depends on a number of variable factors, the agency cannot in advance describe precisely the degree to which particular drug products might be altered through dosage level changes, dosage form changes, or changes in the intended patient population and stay within the exemption. As guidance, the agency will, on request, provide advice on the applicability of the exemption to particular drug uses, and will provide public notice when specific situations are identified that would require an IND.

Some general examples may nonetheless be stated. The agency believes that, in general, the use in a clinical investigation of a drug in capsule form that is lawfully marketed in tablet form should not, in itself, raise safety concerns necessitating submission of an IND. Of course, there may be exceptions. For example, the agency can foresee circumstances in which reformulation to capsule form of a drug product might so affect its bioavailability as to raise safety concerns warranting submission of an IND. There might also be significant problems involved in grinding up and encapsulating enteric-coated or film-coated tablets. Apart from these exceptions, however, FDA believes that the change from tablet to capsule should rarely result in the removal of a study from the terms of the § 312.2 exemption. In contrast, FDA would presume that any change from one dosage form to an intravenous (I.V.) dosage form (including a change from an intramuscular (I.M.) dosage form to an I.V. dosage form) would significantly increase the risk so as to warrant an IND.

FDA also believes that the substitution of an investigational label for an approved label should rarely, if ever, raise safety concerns triggering the need to submit an IND. Similarly, modifications in packaging and labeling

that do not impair a drug's stability or quality should not remove a product from the terms of the exemption. Indeed, because the study will be investigational, it is expected that the labeling for the drug will be changed to some extent for purposes of the investigation.

2. One comment argued that studies of over-the-counter (OTC) drugs involving dosage levels of the active ingredient lower than the marketed level should be exempted because such studies would invariably pose fewer risks for subjects than would be posed by the marketed version of the drug.

The agency does not believe it is desirable to indicate, apart from the general rule, specific situations in which an IND will not be required. Applying the general rule, however, there would appear to be few situations in which use of an OTC drug at a dosage level lower than the marketed level would raise safety concerns. However, where a drug is used to treat a life-threatening illness or to prevent irreversible damage, safety concerns might appropriately trigger the need to submit an IND.

3. The proposal defined "investigational new drug" to include "a marketed drug that is used for any purpose or in any way other than that described in its labeling * * *." Given this definition, one comment asked whether FDA intended a postapproval study of a labeled indication—an indication that, by definition, would not be deemed investigational—to be subject to IND requirements.

The agency believes that a postapproval study of an indication contained in a marketed product's labeling (whether conducted by a commercial sponsor or otherwise) is, and should be, subject to all relevant requirements governing the investigational use of drugs, including the requirements of Part 312. All studies, including those involving use of a marketed drug for a labeled indication, pose risks that patients' interests will be subordinated to the interests of the study, and therefore implicate FDA's responsibilities for the rights and safety of human subjects. To clarify the agency's view that it has jurisdiction over all clinical studies, the definition of "investigational new drug" has been revised to make clear that it includes any drug used in a clinical investigation.

It should be emphasized that even though a study of a marketed drug involving an indication contained in the product's approved labeling would be subject to all relevant requirements governing the use of investigational drugs, such a study would, like a study

of a marketed drug for an unlabeled indication, be exempt from IND submission requirements if it met the conditions of § 312.2.

4. Several comments expressed concern that the proposed exemption from IND submission requirements did not extend to studies intended to support a significant change in the advertising for the drug. One comment argued that studies used to support advertising claims are rarely submitted to FDA and that it is the responsibility of the party making the claim to ensure that support for the claim is adequate. Another comment contended that the reference to advertising in the prohibition is inappropriate as current regulations provide that advertising must be based on drug's approved labeling and many studies are done for the purposes of making comparative statements within the parameters of approved labeling. This comment urged that the exemption from IND submission requirements should apply unless the purpose of the study is to make a significant change in the approved product's labeling. Finally, one comment argued that, given Federal Trade Commission jurisdiction over advertising for OTC drugs, a study to support an advertising claim for a nonprescription drug is not a study subject to the general jurisdiction of FDA.

The agency disagrees with the suggestion that it lacks authority to regulate studies of OTC drugs in human subjects that are conducted for the purpose of modifying drug advertising. Such studies, like clinical studies intended to change prescription drug advertising, involve the use of a human drug for an investigational purpose and are, therefore, appropriately subject to all rules administered by FDA governing the protection of human subjects. However, given that FDA does not routinely become involved in reviewing OTC advertising content, the case for requiring IND's for OTC advertising studies is not as compelling as it is for prescription drug advertising studies. For this reason, FDA has revised the final rule to exempt OTC advertising studies from IND submission requirements.

5. Several comments requested assurance that the results of a study conducted under the exemption in § 312.2 could later be submitted in support of a marketing application. One comment contended that a refusal to accept studies would be unnecessarily wasteful of limited resources and would expose human subjects to unnecessary clinical experimentation.

FDA advises that a study that is conducted in good faith under the terms of the exemption in § 312.2 (i.e., without the filing of an IND) will later be acceptable to the agency in support of an IND or marketing application.

Therefore, where the agency finds that a study was conducted under the exemption on the reasonable belief that each of the significant elements of the exemption applied, the FDA will not subsequently raise any objections to its acceptance, assuming adequate guarantees of the ethical propriety and scientific validity of the study. On the other hand, where there is evidence that the sponsor had no reasonable basis for concluding that a study should have been exempted, FDA may take other regulatory action, as appropriate.

As FDA is willing to discuss and advise sponsors on the applicability of the exemption to planned clinical investigations, the agency believes there should be few occasions for determining after the fact that a study did not qualify for the exemption, but should have been conducted under an IND.

6. One comment recommended that the proposal be clarified to indicate that the exemption for lawfully marketed drug products was confined to drug products lawfully marketed in the United States.

Because approval requirements may differ among countries, the agency intended to limit the exemption to studies involving drugs lawfully marketed in the United States. FDA has revised the regulation accordingly.

7. One comment expressed concern that the determination of whether a drug study "increased the risks" of the drug was very judgmental, and that the degree of judgment involved would lead conscientious investigators routinely to solicit agency help in determining whether an IND is needed. On the other hand, another comment suggested that the provision is so ambiguous that its usefulness is likely to be limited by fear of transgressing. The comment claimed that without a definition of what is meant by "significantly increases the risks," the provision could well tie an investigator to the dose, route of administration, and patient population identified in the approved labeling.

The exemption is not intended necessarily to tie the investigator to the dose, route of administration, and patient population(s) described in the product's approved labeling, but rather is designed to permit deviations from the approved labeling to the extent that such changes are supported by the scientific literature and generally known clinical experiences. As noted in the preamble to the proposed rule, FDA

recognizes that a considerable amount of professional judgment must be exercised in determining whether the conditions of an investigation "significantly increase" the risk associated with use of the drug. Because the assessment of risks involved in a therapeutic procedure is an everyday part of the practice of medicine, the individual investigator should usually be able to determine the applicability of the exemption. As noted, FDA will provide advice on the question when requested.

8. One comment argued that in some cases where a drug is approved for use at a high dosage level to treat a very serious illness, it may not be appropriate to use it investigational at that dosage level in the study of a less serious condition. The comment suggested that such uses should not be exempted from IND requirements.

The comment correctly identifies a defect in the proposed exemption scheme. Under the proposal, an IND would be required only if a change "significantly increase[d] the risks associated with use of the drug." However, in the case cited in the comment, a change in patient population arguably would not affect the risks at all ("risks" understood as the incidence or seriousness of adverse drug reactions), but would plainly affect the acceptability of those risks ("acceptability" incorporating the notion of drug benefit and understood as the willingness of a patient to run the risks associated with the drug to undertake the proposed therapy). FDA concludes that a change that significantly diminishes the acceptability of the risk raises safety concerns that necessitate submission of an IND, and has revised the regulation to incorporate this concept.

9. A comment urged that "patient population" as used in proposed § 312.2(b)(1) be defined specifically. The comment asked whether "patient population" referred solely to demographics, such as age, sex, or race, or also referred to disease groups, such as heart patients or kidney dialysis patients. The comment claimed that if disease groups were intended to be included, it could be that any use outside the labeled indications would constitute use in a different patient population, and that the inherent risk of failure for the nonlabeled use could constitute a significant risk.

"Patient population" was intended to include groups defined in terms of demographic characteristics (e.g., geriatric patients, pediatric patients) and in terms of disease processes (e.g., heart patients or kidney dialysis patients). Therefore, a significant increase in risk

(or significant decrease in acceptability of risk) resulting from the clinical use of a drug in either a demographic or disease group that is not identified in the marketed labeling for the drug would necessitate submission of an IND.

The agency advises that the risk that a drug will not be effective in a patient population should not ordinarily trigger the need to submit an IND. Of course, there should be some evidence to support the reasonableness of a drug's administration for its investigational use. Also, where the consequence of therapeutic failure is irreversible injury or death, an IND would clearly be required. In other cases, because the possibility that a drug may not be effective is obviously relevant to an evaluation of its benefits and risks, the possibility of therapeutic failure should be considered in determining the acceptability of risk of an investigational use (see response to paragraph 8, above).

10. One comment contended that not all IRB's consider their involvement necessary in the circumstances described in proposed § 312.2 under which a drug study would be exempted from IND requirements.

FDA has retained a requirement for IRB review as a condition for the exemption because the agency considers review of such studies to be necessary to protect the rights and welfare of subjects. FDA believes that the generalized concern about IRB unwillingness to review studies is more theoretical than real. In the past, FDA has found little reluctance on the part of IRB's to review studies that are subject to agency regulations mandating such review. However, even if an investigator is faced with an IRB unwilling to review a planned study, the investigator may relocate the investigation to an institution whose IRB is willing to review the study or may request a waiver of IRB review (perhaps for the reasons that lead the unwilling IRB to conclude review was unnecessary). Therefore, the agency believes there should be adequate alternative means of complying with the conditions for exemption.

11. One comment objected to the statement in proposed § 312.2(d) that the investigational drug regulations do not apply to the use of a lawfully marketed drug in the practice of medicine for an unlabeled indication. The comment argued that such an exemption deprived the agency of the control required to ensure the safest possible use of the drug, and also deprived the public of useful information about the drug's nonlabeled uses.

As noted in the preamble to the proposed rule, it was clearly the intent of Congress in passing the Federal Food, Drug, and Cosmetic Act that FDA not regulate the practice of medicine, which the agency has consistently viewed as including the use by physicians of marketed drugs for unlabeled indications in the "day-to-day" treatment of patients. Once a drug product has been approved for marketing, a physician may, in treating patients, prescribe the drug for uses not included in the drug's approved labeling. Control of the practice of medicine in these cases is primarily exercised through State laws affecting medical licensing and practice and through products liability law.

While FDA does not regulate physicians' uses of approved drugs for unlabeled indications, the agency does continue to receive information about the drug's unlabeled uses. This information is obtained from a variety of sources, including physicians' adverse reaction reports, reports of sponsors' postmarketing surveillance activities, and reports of studies conducted by practitioners and researchers that are published in the medical literature.

12. Section 312.2 deals with exemptions from IND requirements for biological in vitro diagnostic products. As proposed, the section specified the criteria for exemption—exempting products intended to be used in a diagnostic procedure that confirmed the diagnosis made by another, medically established, diagnostic product or procedure—but did not specify the particular products that would meet these criteria and therefore be exempt from the otherwise applicable provisions of Part 312. To ensure that the scope of this exemption is not misinterpreted, FDA has revised § 312.2(b)(2) by adding new § 312.2(b)(2)(ii) to identify the specific classes of product that, in the agency's view, meet the criteria for exemption. As thus revised, the regulation lists three classes of exempted products: blood grouping serum, reagent red blood cells, and anti-human globulin. A sponsor of a study involving an investigational biological in vitro diagnostic product not on this list who nonetheless believes the product meets the criteria for exemption should discuss with FDA the appropriateness of extending the exemption to that product. If FDA agrees with the sponsor, the sponsor's product will be added to the codified list of exempted products. A sponsor of a clinical investigation involving a biological in vitro diagnostic product that is not listed in

§ 312.2(b)(2)(ii) must submit an IND for that investigation.

The exemption for clinical investigations involving in vitro biological diagnostic products is conditioned on compliance with the labeling and recordkeeping requirements of § 312.160. FDA has revised § 312.160 by adding labeling and record retention requirements appropriate for in vitro biological diagnostic products. Accordingly, as revised, the section requires that shipments of in vitro biological diagnostic products be labeled as follows: "CAUTION: Contains a biological product for investigational in vitro diagnostic tests only." In addition, § 312.160(a)(3) has been revised to require that records of shipments of exempted in vitro biological products be retained for the same record retention period as applies to shipments of investigational drugs subject to IND requirements.

12a. A placebo used in a clinical investigation is an "investigational new drug" as defined in this rule. As a technical matter, this means that an IND would be required for shipment and use of the placebo in a clinical study even when use of the active treatment drug in the study does not require an IND. FDA does not believe that asking for an IND in such cases serves a useful purpose. Therefore, on its own initiative, FDA has added new § 312.2(b)(5) to state that an IND is not required when a placebo is used in a clinical study that does not otherwise require submission of an IND.

Definitions and Interpretations (§ 312.3)

13. Several comments criticized the use of the term "investigational new drug application" to identify the sponsor's submission. One comment contended that the use of a term like "investigational new drug exemption" would be more consistent with the applicable statutory provisions and with FDA's decision not to adopt an affirmative approval mechanism. Another comment contended that the term "investigational new drug application" carries the connotation that the submitter of an IND is an applicant rather than a sponsor and must wait for the agency's approval prior to instituting the proposed research. This comment recommended that the term "investigational new drug notice" be adopted.

As noted in the preamble to the proposal, the phrase "investigational new drug application" was adopted because it has come to be almost universally preferred over the more cumbersome, official term—"Notice of Claimed Investigational Exemption for a

New Drug." FDA believes the phrase is consistent with the pertinent provisions of the act and is also consistent with the mechanisms by which an IND goes into effect. Notwithstanding that submitters of IND's do not need to obtain approval, investigational drug studies are still subject to agency review prior to their initiation. Finally, FDA notes that to the extent that "investigational new drug application" carries a connotation for some that affirmative approval is required, the agency has revised the final regulation to define the phrase as synonymous with the former title, i.e., "Notice of Claimed Investigational Exemption for a New Drug." Therefore, FDA believes that little possibility for misunderstanding remains.

14. Although no comments were submitted on the IND Rewrite's proposed definition of "sponsor" and "sponsor-investigator," comments were received on the very similar definitions of these terms that were included in the proposed rule governing the obligations of sponsors and monitors (proposed 21 CFR Part 52). Because of the relevance of those comments to this rulemaking, the comments are summarized and discussed below.

15. One comment urged that a person who provides financial support, but who has no right to receive reports in return, be excluded specifically from the definition of "sponsor." The comment expressed concern about how the definition would affect grants to research institutions.

The agency concludes that no changes in the definition of sponsor are necessary. The definition of "sponsor" does not include the concept of financial support as a characteristic of the sponsor relationship. Someone must, however, conceive of a particular study; someone must plan the study, arrange for financing, facilities, personnel, and other necessities; someone must serve as the focal point for negotiations with other bodies such as suppliers, laboratories, and IRB's; and, if an application for the research is required under the act, someone must assume the responsibilities of a sponsor and be identified as such in the application. Clearly, not all of these tasks need to be undertaken by the same person, but generally one person accepts the principal responsibility for completing these chores. The definition of "sponsor" does not force any particular person to accept this responsibility. Rather, it is flexible enough to permit the parties involved to decide what entity will serve as the sponsor of a particular study. Thus, a person who makes a grant to support an investigational study

would not necessarily be a sponsor, unless identified as such in an application for a research permit. Instead, the recipient of the grant or some other entity may assume the responsibilities of a sponsor.

16. Another comment suggested that the word "initiates" in the definition of "sponsor" be replaced by "requests" to avoid any implication that the sponsor conducts any part of the study. One comment suggested the definition be explicit in excluding universities and medical schools in all but special circumstances.

The word "initiates" is appropriate. The definition of "sponsor" clearly states that the sponsor (other than a sponsor-investigator) does not actually conduct the investigation. The suggestion to substitute the word "requests" for the word "initiates" is rejected.

No basis exists for excluding universities and medical schools from the definition of "sponsor." Although these institutions may seldom initiate a clinical investigation, it is possible that they may do so. When they do, they should be subject to the regulations to assure protection of the rights of human subjects, the safety of all subjects, and the quality and integrity of data resulting from the investigation.

17. One comment objected to the exclusion of corporate sponsors from the definition of "sponsor-investigator" and stated that the creation of a double standard of enforcement for sponsors and sponsor-investigators is both confusing and a violation of equal protection because no need for the differential treatment had been demonstrated. The comment argued that pharmaceutical companies often conduct their own investigations, and that they, as well as independent individual investigators, should not be required to police themselves.

The definition of "sponsor-investigator" is not intended to create a double standard or to discriminate against any one. Rather, the definition reflects the practical necessity of distinguishing between the situation in which a single individual both initiates and conducts a clinical investigation and the situation in which a corporation initiates an investigation that is conducted by its employees. The definition of "sponsor" specifically states that employees of a corporate or agency sponsor are considered to be investigators. In the case of a single individual, it would not be appropriate for that individual to comply with certain sponsor obligations. It would be senseless, for example, to require that the sponsor-investigator monitor himself

or herself. This need for special provisions does not exist in cases where a sponsoring corporation or other entity conducts its own investigations with full-time staff employees. In these cases, the sponsor may assign other employees, or use a contractor, to serve as monitors. Monitoring of such a study is thus possible and feasible.

Labeling (§ 312.6)

18. One comment asked whether the "investigational caution" statement required to appear on each drug label must appear on the labels of small, single-dose containers for which there may be significant space limitations.

FDA believes that the inclusion of the required cautionary statement on the investigational label alerts all persons involved in a drug's distribution and dispensing to the drug's investigational status. As the utility of this message is not a function of the size of the package bearing the label, FDA does not believe it should exempt unit dose packages or other small packages from the requirement. At the same time, FDA is aware that space limitations may occasionally make it difficult to include all required information on the smallest drug package containers, and the agency will consider requests for waivers under § 312.10 of label and labeling requirements on a case-by-case basis.

19. One comment urged that the immediate container label of an investigational drug intended for self-administration include the name and emergency telephone number of the investigator. The comment contended that this provision would facilitate treatment of serious adverse reactions associated with investigational drugs.

FDA is not aware of any problems attributable to the absence of emergency identifier information on investigational drug labels. The agency believes that human subjects have little difficulty in obtaining additional information about investigational drugs when the need arises. In addition, the agency notes that the informed consent form, a copy of which is given to each subject of an investigation, is required to identify the person to contact in the event of a research-related injury. For these reasons, while FDA would strongly encourage sponsors and investigators to develop a system to simplify the process by which subjects may obtain information and assistance in a drug-related emergency, the agency does not believe it should mandate identification of an emergency name and number.

Prohibition Against Prolonging an Investigation (§ 312.7(c))

20. Several comments objected to the prohibition in proposed § 312.7(c) against a sponsor prolonging an investigation after finding that the results of the investigation appear to establish sufficient data to support a marketing application. These comments suggested that there may be good reasons to delay submission of a marketing application, including a finding that additional data are needed to support an effective marketing plan. One comment suggested that the final regulation retain the current provision of the regulations that allows the sponsor to give reasons for not submitting an NDA.

FDA believes that subjects should not be exposed unnecessarily to an investigational drug when sufficient data to support a marketing application have been obtained. This view is the basis of the proposed requirement. While sponsors will presumably submit marketing applications after deciding that the results of clinical studies support the applications, FDA concedes that there may be sound scientific or other reasons for delaying the submission of an application, and that such decisions are within the discretion of the sponsor. Therefore, the final rule, while continuing to prohibit a sponsor from unduly prolonging an investigation after finding that the results appear to support an application, will no longer require the submission of an application. FDA believes this change meets the concerns of the comments.

21. The final sentence of proposed § 312.7(c) would have required a sponsor to withdraw its IND if it determined that the data would support a marketing application. One comment suggested that there may be valid reasons for continuing a study, even though the results obtained are considered sufficient to support an NDA.

FDA has deleted this provision. FDA agrees that there may be sound reasons for a sponsor to continue an investigation even after determining that the data will support a marketing application. For example, a sponsor might conclude that further studies would be desirable to obtain additional safety data or to study new indications.

Sale of Investigational Drugs (§ 312.7(d))

21a. Elsewhere in this issue of the *Federal Register*, FDA is reproposing new rules regarding the sale of investigational drugs. Comments received on this issue are addressed in

that reproposal. Pending the adoption of a new final rule based on that reproposal, FDA has retained in this final rule the current provisions on sale.

Waivers (§ 312.10)

22. Proposed § 312.10 described the procedures under which FDA may waive any applicable requirement of the IND regulations. One comment complained that the provisions would give FDA too much discretion to dispense with otherwise applicable regulatory requirements. Other comments contended that because waivers should be relatively rarely needed, the granting of a waiver should be a matter of public notice and discussion.

FDA believes the first comment misconstrued the purpose of the waiver provision. The waiver provision was intended to give applicants flexibility to seek alternative ways of complying with the regulatory requirements governing the conduct of clinical studies. The provision does not authorize FDA to waive statutory requirements; nor will the agency waive regulatory requirements, particularly those concerning the protection of the safety and welfare of human subjects, unless sponsors comply fully with the stated condition justifying waivers.

FDA's requirements for the confidentiality of information apply to the existence of IND's and extend to waiver requests that are part of IND submissions. Moreover, FDA believes that the administrative burdens involved in routinely giving notice of requests for waivers would represent a needless encumbrance on the review process and would, given the limited nature of the waiver process, outweigh whatever benefits might flow from such disclosures.

23. One comment suggested that the waiver regulation identify the specific person or office to be contacted to obtain a waiver.

In general, waiver requests regarding IND's should be directed to the division with responsibility for review of the IND. Because this is the same for IND submissions and contacts generally, the agency does not consider it necessary to list the contact point in the rule itself.

Guidelines (§ 312.145)

24. Many comments contended that, to ensure the integrity and scientific validity of technical guidelines, the public should be provided with an opportunity to participate in the creation or modification of these guidelines.

Because FDA recognizes the significant contribution the industry, the medical community, and other members

of the public can make to the development of scientifically sound guidelines, FDA has routinely solicited comment on previous scientific guidelines. With respect to the guidelines that have already been developed to implement the NDA and IND Rewrites, FDA did issue them as draft guidelines before making them final. Any future guidelines will be similarly developed. FDA believes these actions should provide an appropriate degree of public input into the process.

25. A number of comments approved of the proposed policy to issue a list of guidelines applicable to the regulations administered by the Center for Drugs and Biologics. Additionally, one comment recommended that the list of guidelines be published at least once per year in the *Federal Register*. Another comment recommended the establishment of the centralized public archive of guidelines.

The Center for Drugs and Biologics has prepared a list of guidelines that apply to all regulations administered by the Center. The list may be obtained from the Legislative, Consumer, and Professional Affairs Branch, Division of Regulatory Affairs (HFN-365), Office of Compliance, Center for Drugs and Biologics, 5600 Fishers Lane, Rockville, MD 20857. Given the ready availability of this list, the agency does not believe its annual publication in the *Federal Register* is necessary.

With respect to the request for a centralized archive of guidelines, the agency advises that a public file of guidelines is now maintained by the agency's Dockets Management Branch. In accordance with § 10.80 of the agency's regulations, the file maintained by that Branch includes all public comments received in developing the guidelines.

Investigational New Drug Application Requirement for an IND (§ 312.20)

26. One comment noted that, historically, reviewing divisions of the Center for Drugs and Biologics have required a separate IND to be filed for each dosage form of a drug substance under clinical investigation. The comment recommended revising this policy to permit a sponsor to conduct clinical investigations of several different dosage forms under a single IND.

The comment is not correct regarding current agency policy. FDA does not routinely require separate IND's for different dosage forms of a drug substance under clinical investigation. The agency may require separate IND's if separate applications will simplify

agency review of the submissions—for example, if different dosage forms of an investigational drug are assigned to different reviewing divisions. A sponsor with any questions about the appropriateness of submitting a single IND in this situation should discuss the matter with the division responsible for review of the initial IND submission.

Outside Review Boards

27. In the preamble to the proposed rule, FDA discussed the issue of, and solicited comments on, establishing a "dual track" system in which drug sponsors would have the option of submitting IND's either to FDA or to third party, nongovernmental bodies—"Outside Review Boards" (ORB's). ORB's would parallel FDA in performing a "scientific review" of proposed human research studies involving pharmacology, toxicology, chemistry, and clinical issues. The IND's being considered for this dual track system were the initial IND's that cover the first introduction of a drug into humans and the early clinical pharmacology and effectiveness studies (Phase 1). FDA's preliminary view, as stated in the preamble to the proposed rule, was that the dual track system may be unnecessary in light of the many changes contained in the agency's proposed rule.

Six comments supported the ORB concept while 12 comments opposed adopting a dual track ORB system. These comments, both those in favor of and opposed to ORB's, did not raise new issues or arguments from those noted and discussed by FDA in the preamble to the proposed rule. For example, several comments in favor of ORB's stated that the concept was worth trying on a pilot basis, though acknowledging that even a pilot test would require FDA to establish standards or guidelines for their operation. One comment's endorsement of the ORB concept, however, included a recommendation for extension of ORB review to Phase 2, or at least early Phase 2, trials. Comments against the dual track system cited essentially the same arguments previously noted by FDA in the proposal: that there would be no obvious benefit to the use of ORB's in shortening the review time of IND's as FDA now reviews IND's promptly; that "permissive" ORB's might surface, thereby allowing drug sponsors to "shop around" to find favorable reviewers; and that the independence of ORB's might be questioned where the drug sponsor provides large financial grants to the institution establishing the ORB.

FDA has carefully considered three comments and concludes that it would be desirable to consider further the merits of undertaking a pilot project in this area. However, because the comments submitted represented diverse views, even within the regulated community, the agency is now soliciting comments on the following points in order to determine if a pilot test of ORB's should be undertaken and, if so, to identify the best possible candidates for such a pilot program:

(1) Which institutions, organizations, or other entities would be interested in participating in such a pilot program?

(2) Which drug categories should be involved in a pilot program? For example, should the pilot program focus on one category of drugs or should it include a broader spectrum?

(3) What should FDA's responsibilities be, if any, in monitoring the participating ORB in ensuring that there is no conflict of interest of ORB members, and in evaluating the IND's being considered.

(4) To whom would the ORB be accountable (e.g., FDA, Congress, or other oversight organizations)?

(5) What would be the legal liability, if any, of ORB members or their affiliated institutions, for the consequences of the ORB's decisions?

(6) How long should such a pilot program last, what should be the criteria for assessing its success or failure, and who, in addition to FDA, should participate in the evaluation?

(7) Who should fund the ORB participating in any pilot program?

Interested persons are invited to submit specific proposals for participating, including the make-up of its proposed ORB. Proposals should be submitted by April 20, 1987.

Phases of an Investigation (§ 312.21)

28. Several comments contended that both previous and proposed divisions of a clinical investigation into three phases created "uncertainty and ambiguity." One comment recommended adopting instead a two-tiered system in which the earliest clinical pharmacology stages of research—defined to include those closely supervised studies conducted to obtain basic information about pharmacology, toxicology, and pharmacokinetics, and preliminary information about safety and effectiveness—would be subject to less FDA regulatory control. The comments argued that during this "clinical pharmacology" stage FDA should rely more heavily than in the past upon the expertise of investigators and the safeguards employed by institutions conducting clinical pharmacology

studies. The comments concluded that FDA should focus its review on the "clinical development" stages of research, which would include the later stages of research, in which large numbers of subjects are studied to develop evidence necessary to support a marketing application.

Except for the question of whether there ought to be "two" versus "three" phases, the approach of the final rule is generally consistent with that recommended by the comments, both in terms of how the phases of a clinical investigation are defined and how they are regulated. FDA agrees that the clinical investigation process should be divided into an early clinical pharmacology stage (Phase 1) and a later clinical development stage (Phases 2 and 3), and that FDA's control of the earliest studies should be significantly less than over the later stages.

With respect to the question of two versus three phases, to the extent that the entire process is organic and evolutionary, any division into phases or stages is somewhat arbitrary. However, the agency believes that the definition adopted corresponds as well as any with the significant divisions of the investigational process.

29. Several comments recommended that the proposed definitions of the phases delete all references to the size of the subject population that would usually be expected to participate in the three phases of a study. One comment expressed concern that the numbers used to characterize each of the phases for illustrative purposes might come to be viewed as rigid requirements or limits for the number of patients in each phase. Other comments objected that the definitions of the phases did not necessarily apply to studies of biologic drugs, "orphan" drugs, diagnostic products, dosage forms other than the oral dosage form, or to marketed drugs tested for a new use.

The purpose of including these definitions in the regulations is to provide a general yardstick for the development process for new drugs. The agency agrees that the description of the phases may not apply to certain classes of clinical investigations as well as it applies to studies of the classic, previously untested, drug in oral dosage form. However, that fact does not, in the agency's view, reduce the value of the descriptions as guidance in generally describing the nature of each phase. The agency assures sponsors that the description of the phases are not intended as rigid requirements, and that sponsors whose studies do not conform to the norms described in the regulation

will not be disadvantaged in the review of their applications.

General Principles of the IND Submission (§ 312.22)

30. This section states that the agency's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phases 2 and 3, to help assure that the quality of scientific evaluation of drugs is adequate to permit an evaluation of drugs' effectiveness and safety. Accordingly, the agency's review of Phase 1 submissions focuses on assessing the safety of the investigations while the review of Phases 2 and 3 also includes an evaluation of the scientific quality of the investigation and the likelihood that the investigations will yield data capable of meeting statutory standards for marketing approval.

31. Several comments took issue with the agency statement of its objectives in reviewing clinical investigations. One comment argued that it is inappropriate for FDA to review and otherwise regulate the scientific design of Phase 2 and Phase 3 studies to determine whether such studies are likely to yield data capable of meeting statutory standards of marketing approval. The comment argued that "it is in fact expert opinion [that] is necessary to determine if substantial evidence has been provided," that such conclusions "rarely can be made at the outset" of a clinical development study, and that FDA "should not interject itself into the sponsor's developmental program unless there exists risks relative to patients." On the other hand, another comment suggested that it is inappropriate not to consider the scientific quality of a study, even in Phase 1. The comment suggested that concerns about the safety and rights of human subjects and concerns about scientific validity of a study are, in fact, not distinguishable because, according to the comment, "experiments which are poorly designed scientifically expose subjects to unreasonable risks and are, by definition, unsafe."

FDA believes that the final rule, like the proposal, strikes the proper balance between these two extremes. First, the agency believes that its review of the quality of the sponsor's study design in the later stages of an investigation is in the public interest. Such review should preclude unnecessary exposure of human participants to risks in investigations that will ultimately have no scientific or regulatory value. In addition, by screening out poorly designed studies before they are conducted, FDA review should reduce

the time required to obtain the valid evidence to make a decision on a drug's availability. As discussed later in this preamble, however, FDA would not place a clinical hold on a Phase 2 or 3 study, because of study design, unless the design was so deficient that the study could not meet its stated objective of establishing the product's safety and effectiveness.

Agency authority to consider questions of study design in regulating clinical investigations is well-established. The premarketing approval provisions of the statute require that the evidence proffered to demonstrate a drug product's effectiveness consist of adequate and well-controlled trials. The most cost-effective time to make that determination is before a study begins. Indeed, it would be unreasonable for FDA not to advise a drug sponsor, in advance, if the agency determined that a particular study would not yield data capable of meeting statutory standards for marketing approval.

The decision to narrow the focus in Phase I review to issues of safety alone reflects the desirability of reducing regulatory impediments to scientific creativity at this early stage of drug development. Because approximately 80 percent of all early investigations do not lead to marketing applications, the investment of resources that would be needed to assure the best possible scientific design of such studies is not justified, so long as research subjects are not put at risk. Moreover, Phase 1 studies are generally not considered pivotal to marketing approval, but rather are superseded by the later Phase 2 and Phase 3 studies. Of course, Phase 1 issues of study design that impact on research subject safety will remain part of FDA's purview.

32. Several comments addressed the statement in proposed § 312.22(c) that, to aid communications and minimize paperwork, information and data in IND's should, with some exceptions, be submitted only in summary form. While expressing agreement with the thrust of the principle, several comments were not certain what the exceptions referred to in the proposed section were. These comments asked that FDA identify the specific data items that would require detailed information.

FDA believes that the statement fairly reflects the rule's overall approach to submission requirements. However, FDA concludes that the statement should be deleted as it provides no more guidance on submission requirements than can be obtained from an examination of the various specific provisions of the regulation. Additional guidance may also be obtained from

relevant guidelines and from discussions with agency reviewers. FDA has revised the final rule accordingly.

33. One comment, while appreciating the need to eliminate unnecessary paperwork, contended that eliminating raw data from IND submissions would serve to delay, rather than expedite, completion of the IND. The comment contended that raw data are needed to check sponsor and investigator interpretations of data, to spot check, and otherwise to gain a better insight into the application. The comment stated that raw data are especially important in an IND process in which a decision to permit an investigation to begin must be made within 30 days of submission of the application.

The agency believes that the detail and comprehensiveness of information required to be submitted in the IND are adequate to permit successful oversight of the safety and quality of clinical studies. While the agency does not require submission of "raw data" to the IND, information that is of most direct relevance to agency review—including information on the most important animal tests, on previous human experience with the investigational drug, and on adverse experiences during the course of the study—must be submitted in sufficient detail to permit close scientific review. To require routine submission of raw data would not only impose additional burdens on study sponsors without any evident corresponding benefits to FDA, but could well impair FDA's oversight by overloading reviewers with extraneous and irrelevant information.

34. Proposed § 312.22(d) states that when a sponsor-investigator uses a drug that is already subject to a manufacturer's IND, the sponsor may ordinarily refer to the manufacturer's IND to provide the technical information supporting the proposed clinical investigation. One comment, noting that the preamble to the proposal indicated that such incorporation would occur only when permission is granted by the commercial sponsor, urged that the final regulation require the commercial sponsor's permission to be in writing.

FDA agrees that a sponsor-investigator should not be able to rely on proprietary information submitted by a commercial drug firm unless the sponsor-investigator has received authorization to do so. Therefore, FDA has revised the final regulation to condition such reliance on the sponsor-investigator obtaining appropriate authorization from the commercial sponsor.

35. Proposed § 312.22(d) only expressly discussed the possibility that

a sponsor-investigator might incorporate by reference information contained in a commercial sponsor's investigational application. One comment noted that under some circumstances incorporation by reference of information in a marketing application might also be appropriate. The comment urged that the final regulation be revised to accommodate this possibility.

FDA agrees that under certain circumstances—for example, when a marketed drug is studied for a new indication—it would be appropriate to incorporate information contained in a marketing application into a sponsor-investigator's IND. FDA has revised the final regulation accordingly.

IND Cover Sheet (§ 312.23(a)(1))

36. The proposal contained a requirement that the sponsor identify in the application cover sheet the phase or phases of the clinical investigations to be conducted. One comment asked whether the requirement pertained only to those studies to be initiated 30 days after submission of the IND, or whether it also referred to those studies to be conducted under the IND in the future.

The cover sheet should reflect the phase or phases of the study that are intended to be covered by the IND submission. This submission (including protocols and supporting information) may be limited to the studies that will begin immediately after the IND goes into effect or may cover, at the sponsor's option, any or all of the remaining studies planned.

37. The cover sheet includes a commitment by the sponsor that the investigation will be subject to the initial and continuing review and approval of an institutional review board (IRB), and that investigators will not make any deviations from the research plan without IRB approval. Several comments asserted that a sponsor cannot make these commitments for an investigator. The comments suggested that the sponsor should only be required to make a commitment to inform all investigators of applicable requirements, and to monitor them in accordance with applicable regulations.

A sponsor's obligation to monitor its studies to ensure compliance with pertinent regulatory requirements, including IRB review requirements, has been part of the IND regulations for many years, and is now widely accepted as an appropriate sponsor responsibility. Therefore, FDA does not regard as unreasonable requiring the sponsor to commit to ensure compliance by investigators with pertinent IRB

review and approval requirements. FDA does not view this commitment as a guarantee by the sponsor of investigator compliance in every case, but rather as an undertaking to ensure that investigators are fully informed of their responsibilities and to adopt monitoring procedures to minimize the possibility of investigator noncompliance.

38. Proposed § 312.23(a)(1)(vii) would require the sponsor to list the name and title of the person responsible for evaluating adverse reactions or other evidence of risks obtained from clinical investigators. Several comments recommended that this requirement be deleted, suggesting that the evaluation of adverse reactions is normally a collective effort, involving a number of individuals from different disciplines. The comments suggested that, in many cases, it would be extremely difficult to identify a single individual responsible for decisionmaking in this area. One comment suggested that FDA's initial contact point on all issues relating to conduct of the investigation, including adverse reactions reporting, should be the person responsible for monitoring the conduct and progress of the clinical investigation whose name would already have been provided to the IND under § 312.23(a)(1)(vi).

The agency believes that the requirement should be retained. The identification of a person (or persons) responsible for evaluating information relevant to the safety of the drug will be of significant help to agency reviewers in obtaining more information from the sponsor about a safety report submitted under § 312.32, when such followup is necessary.

FDA acknowledges that the evaluation of safety information may involve more than one person. Therefore, if a number of persons from different disciplines are involved in the evaluative effort, FDA would have no objection to the sponsor identifying any one or more of these individuals. FDA does not believe that it is consistent with the requirement for the sponsor to identify here the person identified in § 312.23(a)(1)(vi) as charged with monitoring the conduct and progress of the investigation unless that person is also, in fact, responsible for review and evaluation of safety information.

As proposed, the regulation would have required the identification of the person responsible "for evaluating adverse reactions or other evidence of risk ***." This has been revised to require the identification of the person (or persons) responsible for "review and evaluation of information relevant to the safety of the drug." The change conforms this section to the provisions

in § 312.32 governing review and reporting of safety information.

IND Content and Format—General Investigational Plan (§ 312.23(a)(3))

39. Many comments opposed the proposed requirements for a general investigational plan (proposed § 312.23(a)(4); final § 312.23(a)(3)(iv)). Several comments suggested that the information submitted in the plan would also be available elsewhere in the IND application. On the other hand, other comments criticized the requirements for the plan as being too vague. One comment strongly disputed the need to provide the required information in the plan, arguing that the clinical development plan of a drug product is not within the realm of information needed for FDA, either to decide whether it is safe to proceed with a clinical study, or to evaluate the scientific merit of a particular clinical study. Additionally, the comment contended that the information requested for the plan is often not available at the time of a new IND submission. The comment concluded that the requirement may force sponsors to formulate plans prematurely at the time of IND submission rather than at a later stage, when sufficient data are available upon which a more concrete plan may be based.

FDA believes that many of these comments misunderstood the limited purpose of the general investigational plan, which is to give agency reviewers a very brief overview of the scale and kind of clinical studies to be conducted during the following year. This overview, which is general should be no more than two or three pages in length, will provide the necessary context for FDA reviewers to assess the sufficiency of technical information to support future studies and to provide advice and assistance to the sponsor.

FDA does not agree with those comments that suggest that the requirements for the general investigational plan are either too vaguely expressed or are redundant with respect to other requirements in the IND regulations. In general, the information submitted in the general investigational plan regarding the sponsor's short-term plans for clinical studies—the indications to be studied, the rationale for the study, the number of subjects to be involved—will not be available in the clinical protocols or elsewhere in the application.

FDA does view this requirement as forcing the sponsor to formulate plans prematurely. When development plans are not yet crystallized, the sponsor

should simply so indicate in the appropriate place in the plan.

Finally, the agency has clarified the regulation to state that the general investigational plan is to be limited to the plans for the following year. As noted in the comments, it would be unreasonable to require a sponsor to formulate and describe its plans for a 4- and 5-year study on "day 1" of the initial trials.

40. One comment asked whether the brief description of the overall plan for investigating the drug would include plans for nonclinical investigations, or whether it would be confined to plans for clinical studies only. Another comment asked whether a sponsor would be required to adhere to the general investigational plan, or would be permitted to make adjustments during the course of the investigation.

The general investigational plan is intended to be limited to plans for clinical studies in the coming year. It is not the appropriate place to discuss plans for animal or other nonclinical tests.

FDA neither insists that a sponsor adhere to the general investigational plan nor does it necessarily require that the sponsor inform FDA of a deviation at the time the deviation is made. The sponsor is free to make changes in the plan during the course of the year as the need may arise, subject to the reporting requirements for protocol amendments and information amendments (§§ 312.30 and 312.31).

41. One comment recommended that the reference in the general investigational plan (proposed § 312.23(a)(4)(vi); final § 312.23(a)(3)(iv)(f)) to "special risks anticipated" should be made consistent with similar references with respect to information in the investigator's brochure (proposed § 312.23(a)(5)(v)) and information the sponsor is required to submit with respect to previous experience with the drug (proposed § 312.23(a)(9)(i)). The comments suggested that all three sections use the wording of proposed § 312.23(a)(9)(i): "Information that is relevant to the safety of the proposed investigation." Alternatively, the comment suggested that the three sections incorporate the wording in the current IND regulations: "All relevant hazards, contraindications, side effects, and precautions suggested by prior experiences."

Although FDA favors consistency whenever appropriate, the comment erroneously assumes that the information to be submitted in the three sections would be identical. In fact, each of the sections calls for somewhat

different information, and different requirements are therefore warranted.

The distinction between the "special risks" section of the general investigational plan and the "possible risks" provision in the investigator brochure is primarily one of scope and detail. Although both sections should contain safety information that may be relevant to precautions and special monitoring to be done during the clinical investigation, the agency expects the general investigational plan to be a more selective document than the investigator brochure. Accordingly, FDA believes that the "special risks" section of the general investigational plan should be limited to those risks that most concern the sponsor—the most serious and significant risks that can be anticipated on the basis of previous experience. FDA has revised the final rule to reflect this distinction.

Finally, the information to be reported in § 312.23(a)(9)(i) is limited to previous human experience with the investigational drug, in contrast to the information expected in the general investigational plan and the investigator brochure, both of which should include animal test data as well.

Protocols (§ 312.23(a)(6))

42. This section would require a protocol for each planned study. Two comments asked whether "planned study" meant a study definitely planned, or a study to be conducted in the future if the investigation followed the desired course. One of these comments noted that protocols may not yet have been completed for some studies to be conducted at later stages of the investigation.

As noted above, the sponsor may limit the IND submission to the study or studies to be conducted at the end of the 30-day review period, or may also include some or all of the studies to be conducted subsequently. To the extent that protocols for future studies have not yet been developed, the sponsor is under no obligation to submit them in the initial submission.

43. Several comments criticized the provision in proposed § 312.23(a)(6)(i), which requests that protocols for Phase 2 and Phase 3 investigations "be designed in such a way that, if the sponsor anticipates that some deviation from the study design may become necessary as the investigation progresses, alternatives or contingencies to provide for such deviation are built into the protocols at the outset." One comment contended that in some cases it may not be possible to anticipate deviation at all, or it may not be possible to anticipate deviations in

sufficient detail to provide for an alternative course of conduct.

Comments suggested that inclusion of such contingency plans should be at the discretion of the sponsor and that such information should only be required "where feasible."

The final regulation, like the proposal, puts the inclusion in the protocol of contingency plans at the sponsor's discretion. Nevertheless, the agency strongly encourages submission of such plans as it believes there is much to be gained in thinking about and planning for possible alternative courses of action early in the protocol development process. Providing in the initial protocol for possible departures from the study design enhance the value and reviewability of study results. Such advance planning also permits both FDA and the sponsor to raise useful questions about study design and supporting information at the earliest possible time. Moreover, to the extent FDA is aware in advance of how a sponsor may need to depart from a planned protocol, misunderstandings between FDA and sponsors over such departures may be minimized.

The agency agrees with the comment that in some cases it may not be possible to anticipate the need to depart from the planned protocol and, in such cases, the sponsor would not be expected to submit plans for alternative or contingent courses of action.

44. Several comments objected to the requirement that the sponsor submit a curriculum vitae for each investigator. One comment suggested that instead of the curriculum vitae, which can extend to 30 or 40 pages, a sponsor should be able to submit a shorter data sheet on each investigator.

Under section 505(i) of the act (21 U.S.C. 355(i)), the agency is required to assure that the investigational drug will be provided to "experts qualified by training and experience to investigate" a new drug. To discharge that responsibility, FDA must have sufficient information about an investigator to show that he or she is qualified by reason of training and experience to conduct the proposed study. While this information is ordinarily most conveniently provided through a conventional curriculum vitae, the agency will accept any other statement of qualification that demonstrates the investigator's fitness to conduct the study. FDA has revised the final regulation accordingly.

45. Several comments contended that the names of each investigator, subinvestigator, and IRB should not be included in the protocol for the investigation, but should be included as

a separate part of the study documentation. One comment claimed that when multicenter studies are conducted, it is more efficient for all investigators to conduct their studies using a master protocol that is individualized only for investigator name and address. The comment observed that, in multicenter trials, investigators are frequently added or changed during the course of the study.

To promote efficient review of an IND, all information pertaining to the protocol, including the names and qualifications of the investigators and identification of participating IRB's, should be presented together. However, whether the information pertaining to the investigators and IRB's is part of the protocol itself, or is an addendum to the protocol or accompanying document, is a matter on which the sponsor may use its discretion. When this issue arises, FDA will be willing to discuss such alternative ways of presenting the information.

When a multicenter study is conducted under a single "master" protocol, the sponsor is not required to resubmit the protocol for every new investigator added, but under § 312.30(d) may simply reference the protocol in an appropriate protocol amendment submission containing information on the new investigator, subinvestigators, or IRB.

46. Another comment suggested that information in the protocol on investigator qualifications redundantly repeated information on investigators provided in the investigator statement (Form FDA-1572).

While it is true that the investigator statement, including information on the investigator's qualifications, is provided by the investigator to the sponsor of the clinical investigation, the sponsor is not required to submit that statement to FDA. Therefore, it cannot take the place of information contained in the sponsor's submission to the agency. At the same time, FDA acknowledges that in the past some sponsors have submitted information to FDA on their investigators by simply attaching copies of the investigator statements from the investigators. The agency believes that such a practice is appropriate provided the investigator statements submitted by the sponsor contain sufficient information to demonstrate the investigators' qualifications to undertake the proposed studies.

47. One comment asked that the term "subinvestigator" be defined. Specifically, the comment questioned whether the term included nonphysicians, nurses, technicians, and

other assistance to the clinical investigator.

Studies frequently are conducted by a team of individuals who share responsibility for designing and conducting the investigation. The principal investigator is the responsible leader of that team. Subinvestigators include all other professionals who assist the principal investigator in the design and conduct of the investigation. Subinvestigators would not include those technicians and other assistance who assume no responsibility for the conduct of the study. FDA has revised the rule to reflect this concept of "subinvestigator."

48. Several comments objected to requiring the sponsor to identify the reviewing IRB for each participating investigator. One comment argued that information on IRB's may not be available at the time that an IND is filed. Another comment argued that it is inappropriate and impracticable to include the name and address of each reviewing IRB, contending that normally the investigator is the IRB contact. The comment asked whether, in requiring the identification of the IRB in the protocol, FDA intended that IRB approval be obtained before the pertinent protocol is submitted to FDA. Several comments concluded that FDA can always obtain the identification of IRB's if a need exists, but that such information should not be part of the protocol or sponsor's responsibility.

This requirement is based on FDA's regulatory responsibility to ensure that the safety, rights, and welfare of human test subjects are adequately protected. To carry out this responsibility, FDA conducts on-site inspections of both clinical investigators and IRB's. By identifying the reviewing IRB in the protocol submission, FDA is assured of having an up-to-date record of active IRB's, together with studies under their purview. FDA believes that requiring sponsors to include this information in their submissions constitutes a minimal burden and will substantially aid the agency in carrying out its mandate to monitor subject safety.

As noted in response to paragraph 67, the final rule requires that IRB approval precede the start of a clinical study but does not require that IRB approval be obtained before the IND is submitted to the agency. If information on the IRB is not available at the time the protocol is submitted, the sponsor may later add the information to the protocol through a protocol amendment.

49. One comment suggested that the protocol provisions be revised to include a requirement that the sponsor state the criteria by which effectiveness of the

investigational drug will be judged. Another comment argued that the protocol should include a proposed method of analysis of results of the study.

The protocol section lists the essential elements that protocols for all studies possess in common. As not every protocol contemplates a specific method of analyzing study results or is intended to examine a drug's effectiveness, it would not be appropriate to list them in this section. The essential elements of a protocol for a study intended to demonstrate effectiveness are described in the regulation outlining the characteristics of an adequate and well-controlled investigation (21 CFR 314.126).

Chemistry, Manufacturing, and Control Information (§ 312.23(a)(7))

50. A comment agreed with FDA that the amount of chemistry, manufacturing, and control information should be less in the clinical pharmacology stage (Phase 1) than in later stages of drug development, but suggested that the proposed chemistry requirements for Phase 1 would still require more information than is necessary to assure subject safety in early research. Specifically, the comment urged that, rather than provide information on the "general method of preparation of the drug substance" for Phase 1 studies, sponsors should only be required to provide a brief outline in the form of a schematic diagram outlining the manufacturing process. Additionally, the comment recommended that sponsors should not be required during Phase 1 studies to provide detailed information on raw materials used in investigational products.

FDA does not agree that it is asking for more information than is actually needed to assure human subject safety in Phase 1 studies. In general, a schematic diagram of the process by which the drug substance is synthesized, while a useful symbolic representation of the method of drug synthesis, will not provide adequate information about the manufacturing process—including, for example, information on equipment used, work-up and isolation procedures, purification steps, tests for completion of reaction and yields—to permit FDA to make a number of key safety determinations, including determinations about the presence of contaminants and byproducts.

51. Several comments urged that the proposal be revised to indicate that complete stability data are not required prior to beginning clinical studies. These comments urged that the regulations permit the development of stability data

concurrently with the conduct of the clinical investigations. One comment argued that in the closely controlled distribution system that is required for investigational drug accountability, corrective action for materials that no longer meet the appropriate standards for use is easily undertaken. The comment contended that the concurrent development of stability data is consistent with current good manufacturing practice. Two comments suggested that if data developed concurrently indicate that a drug product does not meet its acceptance standards during the entire period of the investigation, appropriate corrective action can easily be undertaken to replace the material. Several comments maintained that permitting concurrent stability testing would further the regulatory objective to speed up the drug testing and approval process.

The regulation does not preclude a sponsor from conducting stability tests on an investigational drug product concurrently with clinical investigations of the product. However, the agency does expect that, by the time a clinical study is begun, the sponsor will have submitted to FDA at least preliminary evidence (obtained from accelerated studies) to show that the product is likely to remain stable for the duration of the study. The applicable requirements for stability testing are set forth in 21 CFR 211.166 of the regulations describing current good manufacturing practice for finished pharmaceuticals. At the same time, sponsors should be aware that a decision not to complete stability tests before commencing a clinical study may jeopardize the value of study results should the tests ultimately show problems in the drug product's degradation or bioavailability.

While the regulations thus permit concurrent testing of investigational drug products, the agency believes that testing of the stability of the drug substance should be substantially completed before initiation of human clinical studies of the drug. This should not present significant difficulties to sponsors, as these tests are usually conducted while preclinical animal studies of pharmacology and toxicology are underway.

52. The proposed rule indicated that, as drug development proceeds, and as the scale of production of the investigational drug is changed from the limited pilot production appropriate for the initial clinical studies to larger scale production necessary for expanded clinical investigations, the sponsor should submit information amendments to supplement the initial information

submitted on the manufacturing and control processes. One comment argued that information amendments should only be required if the manufacturing formula changes, not every time the scale of production changes, since the scale does not change the compositional formula of the clinical supplies.

FDA does not agree. Although it is true that changes in scale may not affect a drug's composition, such changes may affect a drug's physical or biochemical characteristics and thus possibly affect the safety of proposed studies. Specifically, changes in scale may involve use of new kinds of production equipment or use of the same equipment in different ways to accommodate larger batch processing. These changes may significantly affect important chemical and physical properties of the drug, including the drug's content uniformity, hardness, moisture content, and dissolution. Ultimately these sorts of changes can affect a drug's bioavailability and be of clinical significance.

53. One comment recommended that sponsors be required to provide information on the composition, manufacture, and control of any placebo used in a controlled clinical trial, including information demonstrating that the placebo is identical to the drug under study in all respects other than the presence of the active drug substance. The comment contended that the validity of a blinded study depends in part on the placebo being perceived as identical to the drug under study.

FDA agrees that information on placebos is needed to assure that the blinded nature of a study is not compromised by the failure of a placebo to mimic the odor, taste, texture, and other physical characteristics of the investigational drug. FDA has requested such information for a number of years.

In response to this comment, the agency has revised the final rule to require a brief, general description of the composition, manufacture, and control of any placebo used in a controlled clinical trial. The agency, however, is not requiring a demonstration that, but for the presence of the active drug substance, the placebo is "identical in all respects" to the drug under study. This is because exact duplication of the investigational drug may not be possible. For example, the use of a coloring agent or an inactive bitter flavoring may be required to mimic characteristics of the drug substance so that the placebo will be perceived as identical to the drug under study.

54. As proposed, the rule would permit reference to the United States Pharmacopeia—National Formulary to

satisfy relevant portions of the chemistry section. One comment noted that compendial requirements may in some cases not meet FDA's requirements. The comment urged that the rule make clear that in some circumstances reference to the formularies may not satisfy relevant requirements of the chemistry provisions.

As noted in the preamble to the NDA Rewrite final rule (50 FR 7459), although the agency believes that references to the official compendia may be relied on under proper circumstances to provide the required information, new developments in drug synthesis and advances in analytical technology may introduce new concerns about the chemistry of drug substances that are not adequately addressed by current compendial monographs. In those cases, FDA may need additional information about a drug substance to ensure that additives or byproducts of the synthetic process are properly controlled. Although a reference to official compendia will often satisfy the requirements, the final rule has been revised to indicate that FDA may require additional information to permit proper review of the application.

55. One comment claimed that the information on manufacturing facilities submitted in the IND in accordance with proposed § 312.23(a)(6) would be inadequate to determine whether the applicable IND termination provisions should be invoked, i.e., whether the facilities used for the manufacturing, processing, and packing of the investigational drug are adequate to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for subject safety.

FDA believes that the information required in § 312.23(a)(6) should ordinarily be adequate to determine whether the drug's manufacture and control may compromise subject safety. The required information includes descriptions both of the general method of preparation of the drug substance (§ 312.23(a)(7)(iv)(a)) and of the method of manufacturing and packaging of the drug product (§ 312.23(a)(7)(iv)(b)). If additional information is needed on the manufacture and control of the drug, FDA can either request the sponsor to submit the information, or under certain circumstances, can inspect the manufacturing site to determine compliance with applicable current good manufacturing practice (21 CFR Part 211).

56. One comment suggested using the word "strength" instead of "potency" in § 312.23(a)(7)(iv)(a) to be consistent with the language of 21 CFR Part 211.

FDA agrees and has revised the final rule accordingly.

Pharmacology and Toxicology Information (§ 312.23(a)(8))

57. The proposed pharmacology and drug disposition section would require information describing the pharmacological effects and mechanisms of action of the drug in animals and information on the absorption, distribution, metabolism, and excretion of the drug. One comment asked whether the information on the absorption, distribution, metabolism, and excretion of the drug required under proposed § 312.23(a)(8)(i) should, like the information on pharmacological effects, also be based on animal studies.

The pharmacology and toxicology section (§ 312.23(a)(8)) refers principally to data derived from animal studies, but could include human data for comparison, if available. Therefore, FDA expects that any information in the initial IND submission on the absorption, distribution, metabolism, and excretion of the drug will be derived from animal studies of the drug. As information is obtained on the pharmacokinetics of the drug in humans, the agency would expect such information to be reflected in the investigator brochure (§ 312.23(a)(5)(ii) and (iii)) and reported, as appropriate, in information amendments and annual reports.

58. Proposed § 312.23(a)(8)(ii)(b) would require the submission of full tabulations of data suitable for detailed review for each toxicology study that is intended primarily to support the safety of the proposed clinical investigation. Many comments objected to the requirement that full toxicological data be submitted. Several comments contended that this requirement is inconsistent with the principle that data in the IND should normally be submitted in summary form. Other comments expressed the belief that full data are not necessary in order to achieve the objective of assuring subject safety, arguing that the safety of subjects can be adequately protected by requiring submission of a summary in sufficient detail to permit scientific review, and allowing FDA access to full data when necessary.

FDA believes that, as a general rule, full tabulations of data from subacute and chronic studies and other studies intended primarily to support safety are crucial in permitting their scientific review. The agency has found that summaries, by heavy reliance on statistical averaging of data, may not reveal the actual magnitude of response

in some animals and do not provide for comparing the spectrum of responses in any one animal. Summaries, while helpful adjuncts to the pharmacological and toxicological review process, cannot substitute for full tabulations in providing adequate insight into the extent and course of drug effects in individual test animals.

Because FDA believes that full tabulations of such data are necessary in every case for an adequate review of the safety of proposed studies, it sees no merit in a procedure that would permit reviewers to obtain detailed information only on request. Such a procedure would likely only serve to delay the review process.

59. One comment asked for clarification of the meaning of "full tabulations" of toxicological data. The comment stated that it would object to a requirement that every data point collected in a study be tabulated, suggesting that such a requirement would create an unwarranted burden.

This section is intended to continue current practices with respect to submission of individual animal data. Thus, applicants are not required to submit laboratory notebooks, worksheets, and other documents relating to individual animals. However, the agency does expect the full tabulations to include every significant recorded observation, pathology finding, and laboratory measurement that relates to a scientific evaluation of the drug's safety for its proposed investigational use. This would ordinarily include all notable periodically measured toxic signs, as well as blood values, electrocardiograms, and any other measurements or observations that would contribute to the evaluation of the drug's toxic potential.

60. Several comments urged the adoption of specific pharmacological and toxicological testing requirements. Thus, for example, one comment urged that the regulation clearly require sponsors to test drugs that have not previously been tested in human subjects in at least two animal species prior to the commencement of clinical trials.

As noted above, the regulation is intended to describe in general terms an appropriate format and content for the initial IND submission. Because of the dynamism and complexity of the scientific issues involved, the agency does not believe that it would be either feasible or wise to specify in the regulation detailed, substantive pharmacology and toxicology testing requirements. Current FDA guidelines do specify the type of animal studies

needed for new drug substances before commencement of human studies, and the agency is developing, and will soon make publicly available, an updated guideline that will outline the scope of animal testing submissions for the more common and expected circumstances.

Previous Human Experience with the Investigational Drug (§ 312.23(a)(9))

61. Section 312.23(a)(9)(iii) requires the sponsor to list the foreign countries in which the investigational drug has been marketed as well as those countries in which the drug has been withdrawn from the market for any reason relating to safety or effectiveness. One comment urged that this responsibility be limited to experience with the sponsor's own drug as "it may not be feasible for a sponsor to be fully aware of all actions taken by all firms worldwide."

FDA believes that it is not unreasonable to expect a commercial drug firm to make a good faith effort to determine the foreign marketing experience of a drug it seeks to market in the United States. Given the potential hazardous consequences that may follow from the use of unsafe or ineffective drugs, FDA would expect commercial sponsors to obtain the information for their own benefit, apart from regulatory requirements. Much of this information should already be available to the sponsor as a result of patent searches or other routine business practices. Because additional information on foreign marketing is readily obtainable through trade journals available in the United States, a comprehensive review of the pertinent information should not be unduly burdensome to the sponsor.

62. Proposed § 312.23(a)(9)(i) would require that any published material relevant to an assessment of the drug's safety and effectiveness be provided in full. One comment claimed that this requirement is inconsistent with the general principle that the sponsor should provide a summary of previous human experience. The comment argued that it would be possible to provide relevant information on a number of similar studies in a single narrative summary and that such a summary of the available literature would provide all the information the agency would need. One comment claimed, moreover, that a requirement for all literature could result in voluminous submissions under certain circumstances, especially if a sponsor were testing a combination product in which one component is a well-established drug.

The agency believes that some of these comments may have misinterpreted the proposed provision

the purpose of which is to give agency reviewers easy access to those reports in the scientific literature that are most directly relevant to the safety and effectiveness of the drug for its proposed use. Reports of greatest relevance would include, for example, reports of the most serious or frequent drug-associated adverse reactions, reports of critical dose-response information, as well as reports of the results of controlled clinical trials. Publications from the scientific literature less directly relevant or exclusively relevant to other indications for use need not be submitted, although they should be included in the sponsor's bibliography. Thus, for example, a sponsor studying aspirin to reduce the risk of stroke would not be expected to submit to FDA studies relevant only to the drug's analgesic effects.

If a sponsor were testing a combination drug in which one of the components had already been lawfully marketed in the United States, the sponsor would not need to submit all the literature on the component's marketed use, but only publications of direct relevance to the proposed use (including publications relevant to component-component interactions). FDA has revised the final rule in § 312.23(a)(9)(ii) to make this requirement explicit.

For the reasons given, the agency does not believe that the provision should ordinarily be unduly burdensome or result in the submission of excessive numbers of publications from the scientific literature. Of course, if a sponsor is concerned about the extent of published literature to be submitted in a particular instance, the agency would be willing to discuss the issue with the sponsor in advance of the submission.

63. One comment stated that providing information for each component of a combination product the components of which have been previously investigated or marketed, is reasonable only if the requirement is understood to relate to the active drug components.

FDA agrees and has revised § 312.23(a)(9)(ii) accordingly.

Drug Dependence and Abuse Potential (§ 312.23(a)(10)(i))

64. Proposed § 312.23(a)(10) would require a sponsor of a drug with abuse potential to provide a description of "relevant clinical studies and experience and studies in test animals." One comment asked that this section be clarified to require that such information be supplied only if it is available and only for the later phases of a clinical investigation.

The comment misunderstands the intended function of this section, which is simply to establish a place in the IND for a sponsor to compile and present available information on the dependence or abuse potential of its drug. The provision does not establish substantive requirements with respect to clinical studies. Guidance on these substantive matters can be obtained from the published clinical guidelines issued by FDA and from the agency's scientific review divisions.

*Material in a Foreign Language
§ 312.23(c)]*

65. One comment objected to the requirement that the sponsor submit a copy of each original literature publication for which an English translation is also submitted. The comment claimed that this requirement is of questionable value and is inconsistent with the principles of the Paperwork Reduction Act. The comment suggested deleting the requirement for routine submission and replacing it with a requirement that foreign language materials be made available to FDA on request.

FDA believes that it is reasonable to ask an applicant who relies upon a publication in a foreign language to submit both the foreign publication and an English translation of it. FDA believes it is under some obligation to verify the bases of documents it receives only in translation, and views sponsors' furnishing to FDA of the non-English original as the least burdensome method by which verification can be accomplished.

Protocol Amendments (§ 312.30)

66. One comment suggested that, to speed early clinical research, sponsors should not have to submit protocol amendments: (1) For modifications of a clinical pharmacology research protocol made on the basis of experience gained in the investigation; (2) for continuation of a human subject from Phase 1 to the subsequent phases of the investigation; or (3) in situations where the investigator concludes that immediate action is necessary to reduce or eliminate an apparent immediate hazard to a subject.

The final rule, like the proposal, does not require a sponsor to submit a protocol amendment for a change in a Phase I protocol that may affect the scope or scientific quality of an investigation, if it does not significantly affect the safety of subjects. Therefore, to the extent that a modification to a clinical pharmacology (Phase 1) protocol does not raise significant safety issues, it would not have to be reported in a

protocol amendment. In addition, the protocol amendment provisions do not require a sponsor to file an amendment to continue a subject from one phase of the study to the next, assuming a protocol is in effect for the subsequent phase that covers administration of the investigational drug to that subject.

Finally, as noted in response to paragraph 69 below, FDA has revised the final rule to state that a sponsor may change a protocol to eliminate an apparent immediate hazard to a subject, provided FDA is subsequently notified of the action. The agency believes this clarification of the requirement meets the concerns of the comment.

67. As proposed, protocol changes that would require a protocol amendment under § 312.30(b) may only be implemented after the sponsor has submitted "the amendment to the IND following completion of review of the change by the IRB that is responsible for review and approval of the study." Several comments read this requirement as obliging the sponsor to ensure that an IRB reviewed and approved the change before submitting it in a protocol amendment to FDA.

FDA has revised § 312.30(b) to clarify that IRB review and approval may be obtained before or after submission of the protocol amendment to FDA, provided the sponsor and investigator ensure that the change that is the subject of the amendment is not begun until IRB review and approval has been obtained.

68. One comment argued that the rationale for requiring submission of a protocol amendment to report the addition of a new test or procedure to monitor for side effects or adverse events is unclear, since any effect of such action would be a positive one, increasing the safety precautions afforded the subject. The comment suggested that comparable considerations dictated that changes to enhance the scientific quality of studies should also not require a protocol amendment.

The purpose of a protocol amendment is to give the agency timely notice concerning the kinds of changes that bear directly on its review and monitoring responsibilities. The agency believes it is responsible for making an independent review of significant protocol changes even when their intended effect is to increase the safety of subjects. In this context, it should be noted that submission of a protocol amendment to FDA does not delay implementation of the change described in the amendment.

69. One comment noted that, for protocol changes designed to reduce the

risks of injury, any delay in undertaking the change caused by the need to submit the change to FDA or to obtain IRB approval might jeopardize subject safety. The comments suggested that prior notification to FDA and prior approval by IRB's not be required for changes designed to eliminate hazards to study subjects.

The agency agrees that a protocol change intended to eliminate an apparent immediate hazard to human subjects should not be delayed because of a need to notify FDA or the reviewing IRB. FDA has revised final § 312.30(b)(2)(ii) to permit such changes, provided FDA and the reviewing IRB are subsequently notified.

70. One comment asked the agency to clarify a sponsor's responsibilities with respect to protocol changes that would not require submission of a protocol amendment, including, for example, a Phase 1 change that does not significantly affect subject safety.

The sponsor's responsibility depends on the nature of the change. Changes that are not required to be reported in a protocol amendment may still be reportable under another section of these regulations, or under the regulations governing review of marketing applications (Part 314). Thus, for example, a change in the scope of a Phase 1 investigation may not require a protocol amendment but should be reported in the next annual report in accordance with § 312.33(b). Other changes—minor modifications of a study design, for example—may not be reportable until the study is submitted in a marketing application, where it would be reported as part of the application under § 314.50(d)(5).

Finally, it should be noted that investigators may be required under § 56.109 to report to reviewing IRB's some protocol changes that are made during Phase 1 even though such changes need not be reported to FDA under these protocol amendment requirements.

71. Several comments expressed support for the provision in § 312.30(c) that would require a sponsor to notify FDA within 30 days of adding an investigator, but asked that the final rule make clear that a sponsor may ship an investigational drug to a new investigator at the time that the investigator is added by the sponsor to the study, and that the newly added investigator may begin his or her participation in the study prior to submission of the protocol amendment, so long as the amendment is submitted within 30 days of the commencement of the investigator's participation.

FDA has revised § 312.30(c) to make clear that, once the sponsor has added an investigator to a previously submitted study, the investigator may begin participation in the study. Notification to FDA is required within the next 30 days.

72. Several comments read § 312.30(d)(1)(i) as requiring a sponsor to describe in detail the differences between the new and the old protocols. The comments claimed that this provision would impose significant burdens without corresponding benefits. One comment claimed there are many cases where detailed explanations would not be needed. Finally, one comment suggested that, if a requirement to explain protocol changes is retained at all, a sponsor should only be required to highlight significant changes from previous protocols.

Proposed § 312.30(d)(1)(i) was not intended to require detailed explanations of the differences between old and new protocols. In fact, a detailed and undiscriminating enumeration of the differences would defeat the purpose of this requirement, which is to identify the most important differences between the old and new protocols and to alert FDA reviewers to major changes that may require additional supportive data, such as changes in dose, route of administration, or indication. What is expected is that the sponsor will briefly highlight the most clinically significant features of the new protocol, such as an increase in dose or duration of treatment, or a change in patient population. To clarify agency intent, FDA has revised § 312.30(d)(1)(i) to require, for each new protocol, a brief description of the most clinically significant differences between it and previous protocols. As so modified, the highlighting of the changes should not be a significant burden on sponsors, and will be of considerable help to FDA in directing reviewers' attention to the parts of a protocol most in need of scrutiny.

73. One comment asked for clarification of a sponsor's responsibilities when a new investigator is added to conduct a previously submitted protocol. The comment stated its assumption that FDA would still want all the information that is currently required, including a copy of the protocol itself.

In this situation, the agency does not believe a copy of the previously submitted protocol is necessary, if the protocol is adequately identified in the protocol amendment. However, FDA would expect the sponsor to submit the same information about the individual investigator that would be required if

the investigator had been named at the time the protocol was initially submitted. These items of information are listed in § 312.23(a)(6)(iii)(b) and include, in addition to the investigator's name and qualifications, the name of each subinvestigator, the name and address of the research facilities, and the name and address of the reviewing IRB. FDA has revised § 312.30(d)(1)(ii) to clarify this requirement.

74. Several comments addressed the requirement in § 312.30(d)(2) that the sponsor reference in the protocol amendment the specific information relied upon to support the new protocol or protocol change. The comments claimed that the provision is overly broad and may be read to require extensive cross-referencing to virtually all data in support of every new protocol or protocol change. One comment urged that the section be deleted, claiming that, under most circumstances, new protocols or protocol changes rely not on specific information but rather are based upon the totality of the experience derived from earlier or ongoing clinical trials. Another comment suggested that the final rule be revised to require references only to specific information in support of significant differences in new protocols or in support of significant protocol changes.

In one sense, FDA agrees that every new protocol and protocol change relies ultimately upon the totality of previously submitted information. The intent of the provision, however, is to elicit reference to the specific technical information supporting the clinically significant aspects of the proposed change. Thus, if a sponsor intends to change the dosage form of the investigational drug, appropriate chemistry and manufacturing information supporting this change should be referenced. Or, if a sponsor proposes to increase significantly the duration of patient exposure to the drug, the sponsor should reference the appropriate animal tests that would support this increased human exposure. To the extent that FDA is apprised of the basis for a change in a protocol, it can more quickly and comprehensively review the change. Of course, if the change is one that plainly does not require specific technical support, the sponsor would not be expected to reference any supporting technical information. FDA has revised § 312.30(d)(2) accordingly.

75. Several comments complained that the agency had not justified the use of serial numbering of protocol amendments and expressed doubt about the utility of this policy. One comment claimed that serial numbering will make

tracking more difficult than under the current system, and recommended that an attempt be made to develop a numbering system that will provide for easy access to individual protocols and investigators. The comment suggested that it may be possible, for example, to use prefixes or suffixes to identify the protocol of an investigator to which a specific protocol amendment applies.

As noted in the preamble to the proposal, the formatting requirements for amendments, including the requirements for serial numbering of amendments, are intended to make these submissions easier for FDA to process and review. Deficiencies in formatting have frequently produced a disorderly and sometimes unintelligible flow of amendments and other documents to the IND file. The changes are designed to rationalize this flow of information to permit agency reviewers to gain an understanding of the significance of amendments and their relationship to one another. The changes should also help reviewers determine the completeness of amendments to an IND.

While the agency does not believe that sequential numbering of amendments will somehow make tracking more difficult, FDA agrees with the comment that an identification method that separates protocol changes and new protocols from new investigators might be preferable to a simpler system. The final rule does not mandate the use of a particular method of serial numbering, and so individual sponsors are not precluded from adopting a more complex system. FDA would be happy to work with sponsors in developing a system of maximum usefulness.

76. Section 312.30(d)(3) specifies that if a sponsor desires FDA to comment on a protocol amendment submission, the protocol amendment should so indicate and should include the specific questions FDA should address. One comment suggested that FDA should be obliged to respond within 15 days to a sponsor's request to avoid impeding the progress of the investigation and to avoid the imposition of clinical holds due to deficiencies in a proposed protocol.

Because protocol amendments do not require prior agency approval before implementation, the lack of an agency response should not, in itself, impede the progress of an investigation. Nevertheless, FDA understands the importance of conscientiously reviewing and responding to sponsor requests for assistance, and will respond as quickly as is allowed by the complexity of the

questions, the availability of agency reviewers, and the demands of other priority matters.

Information Amendments (§ 312.31)

77. One comment recommended that proposed § 312.31(b) be revised to define what discipline categories should be used when information amendments are "numbered serially" by discipline.

FDA has revised § 312.31(b) to add examples of appropriate headings for information amendments.

IND Safety Reports (§ 312.32)

What is Reportable?

78. A number of comments expressed confusion about what would be reportable in an IND safety report. As proposed, § 312.32 would require a sponsor to report "Any serious adverse experiences or other information * * * not previously reported (in nature, severity, or incidence) that may suggest significant hazards, contraindications, side-effects, or precautions." One comment asked that the agency define the term "serious adverse experience." Other comments asked that the agency clarify the meaning of "not previously reported (in nature, severity, or incidence)." One comment suggested that the parenthetical phrase was unnecessary and should be deleted. Another comment argued that the severity or incidence of an adverse experience is more appropriately the basis for adverse reaction reporting of marketed drugs than it is for investigational drugs. That comment contended that the appropriate basis for adverse reaction reporting in the IND process should be whether an event is "alarming," alarming being defined as any event requiring the discontinuation of an IND.

FDA agrees that it will be useful to provide additional guidance on what information should be reported in an IND safety report. The goal of the safety report section is to ensure timely communication of the most important new information about experiences with the investigational drug. To better achieve that goal, FDA has revised the safety report requirement to require reporting of any "adverse experience associated with the use of the drug that is both serious and unexpected." To clarify further a sponsor's reporting obligation, the agency has further revised the final rule to codify definitions of "serious adverse experience" and "unexpected adverse experience."

Serious Adverse Experience

Under this final rule, "serious adverse experience" is defined to mean any experience that "suggests a significant hazard, contraindication, side effect, or precaution." The definition distinguishes human (clinical) experiences from drug-related experiences in laboratory animals. "Serious adverse experience," as it applies to human experience, is defined as any experience that is fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose. (This definition is identical to a proposed revision of the definition of "serious" adverse drug experience for purposes of postmarketing reporting of adverse drug experiences published in the *Federal Register* of December 30, 1986 (51 FR 47028).) In contrast, with regard to results obtained from tests in laboratory test animals, a serious adverse drug experience includes any experience suggesting a significant risk for human subjects, including any finding of mutagenicity, teratogenicity, or carcinogenicity.

The language "suggests a significant hazard, contraindication, side effect, or precaution" is taken directly from the current IND regulations, § 312.1(a)(6), and the IND proposal, § 312.32(b). Thus, the underlying standard for determining what is a serious adverse drug experience has remained constant over time. The additional examples of serious human adverse drug experience are taken from the NDA Rewrite final rule, § 314.80 (50 FR 7500), pertaining to reports for marketed drugs. These examples have been added in order to clarify the underlying standard and to provide continuity in reporting between the investigational and marketing stages.

Unexpected Adverse Experience

In proposing to require a sponsor to report adverse experiences "not previously reported (in nature, severity, or incidence)," FDA intended to ensure the timely communication of the most important new information about the drug. However, the agency has concluded that the "not previously reported" language is unsatisfactory in that it might be read as limiting safety reports to the first case of a particular adverse experience. This was not intended. While the report of the first case of an adverse experience may indeed be the most useful one in terms of alerting FDA to a potential safety problem, reports on the first case are usually not adequate to determine whether or not an experience is truly

drug related, to evaluate its likely frequency, and otherwise to assess the significance of the risk posed. To avoid any possible misinterpretation of agency intent and to ensure continued reporting of cases of a serious adverse experience until the risk posed is reasonably well characterized and understood, the agency has deleted the "not previously reported" phrase, and substituted for it a requirement that sponsors report "unexpected" experiences.

The final rule defines an "unexpected adverse experience" to mean any adverse experience that is not identified in nature, severity, or frequency in the current investigator brochure for the study. For those IND's for which an investigator brochure is not required (i.e., IND's conducted by sponsor-investigators), an unexpected adverse experience would include any experience that is not identified in nature, severity, or frequency in the "risks" information contained in the current application. This definition is analogous to that used in the NDA Rewrite for reporting adverse drug experiences on marketed drugs, where the term "unexpected" is defined as any serious adverse experience outside of the drug's approved labeling (see § 314.80(a); 50 FR 7500; February 22, 1985). Under the final rule, therefore, a serious adverse reaction that had been reported previously could still be unexpected.

To increase assurance that the significance of safety information will be placed in proper context, the final rule also requires that the sponsor identify all safety reports previously submitted by the sponsor concerning a similar adverse experience, and analyze the significance of the adverse experience in light of all previous similar safety reports.

Finally, FDA disagrees with those comments that suggest that it is inappropriate to base IND safety reporting on adverse experience severity or incidence. A study under an IND is allowed to proceed in part on the basis of the sponsor's characterization of the risks posed by the investigational drug. This characterization, usually described in some detail in the investigator brochure and elsewhere in the IND, is based primarily on the clinical and nonclinical experiences with the drug available at the time studies under the IND begin. As additional experience with the drug is obtained that either suggests new risks or casts previously identified risks in a new light, it is essential to FDA's safety monitoring responsibilities that the agency be promptly apprised of such information.

79. Under the final rule, a sponsor would be required to report each successive case of a serious and unexpected adverse experience until the risk posed by the experience is sufficiently well understood to be described in the investigator brochure or until an equally satisfactory resolution of the issue is reached (for example, a determination that the experience is not drug related). Ordinarily, reports of succeeding cases would, like the report of the first case, be submitted in IND safety reports as soon as possible and in no event later than 10 working days after the sponsor's initial receipt of the information. However, in some situations it may be desirable for the sponsor to "group" such cases at some different frequency, or to report such cases in a format not conventionally used for reporting a single case. Therefore, the agency has revised the final rule to authorize FDA to require a sponsor to submit safety reports in a format or at a frequency different than that normally required (§ 312.32(c)(3)). Section 312.32(c)(3) also permits the sponsor to propose and adopt an alternative reporting arrangement, if the alternative is agreed to by the director of the division of FDA's Center for Drugs and Biologics responsible for review of the IND.

Review Requirements

80. Several comments objected to the proposed requirement in proposed § 312.32(a) (now § 312.32(b)) that a sponsor "immediately" review all information relevant to the safety of the drug. One comment contended that the immediate review requirement was unrealistic, given that a sponsor may receive hundreds of medical journals within a short period of time, not all of which can be reviewed "immediately," and some of which may require translation into English.

FDA expects a sponsor to review all information it receives that may be relevant to the safety of its investigational drug in sufficient time to meet its reporting obligations. However, as noted below, FDA has deleted the proposed 3-working-day time frame for written reports of fatal or life-threatening experiences and has established a uniform, 10-working-day time frame for all written reports of serious and unexpected adverse experiences. (As noted below, sponsors are still required to give FDA an "early warning" by telephone of any information obtained from the sponsor's own clinical studies suggesting an unexpected fatal or life-threatening experience no later than 3 working days after receipt of the information.) This

means, in effect, that sponsors who would have had no more than 3 working days to review and report safety information under the proposal will now have up to 10 days to complete their review and submit required reports. In light of this change, the agency believes a "prompt review" requirement is a more accurate characterization of a sponsor's reporting obligation and has revised § 312.32(b) accordingly.

81. One comment asked that FDA clarify when it would impute to a large, multi-national corporation knowledge of an adverse event gained by one of its employees. In particular, the comment wanted to know when FDA would deem a parent company to have "received" a report in a medical journal obtained by an employee of one of the parent company's subsidiaries.

FDA expects drug companies to review those reports that come to its attention in the normal course of business. Whether an employee's knowledge of a report of an adverse experience would be imputed to the sponsor will depend upon the factors surrounding the employee's knowledge of the report. As a general rule, however, FDA will consider a drug firm responsible for information known to its employees (including the employees of a division or separately incorporated subsidiary of the firm), and companies should adopt procedures to ensure that employees will expeditiously bring important information to the attention of company officials.

82. Several comments objected to the requirement that sponsors review and report in safety reports information about "related drugs." Suggesting that the term might be variously construed to include drugs with related chemical structures, drugs of the same pharmacological class, and drugs with the same intended therapeutic use, the comments criticized the term as vague and potentially subject to an overbroad interpretation. One comment complained that the provision would impose a greater reporting burden on IND sponsors than that imposed on holders of approved marketing applications.

The agency agrees that the category of "related drugs" may be overbroad, and that a requirement based on that category might well elicit much information of little relevance or value to FDA's safety evaluation of a particular investigational drug. Therefore, the agency has deleted the requirement that expressly calls for sponsors to report in safety reports information about related drugs. As revised, the regulation limits safety

reports to those experiences that are associated with use of the particular investigational drug under study. This revision is not intended to suggest that safety information about related drugs is never important to evaluating the safety of an investigational drug. Indeed, a drug firm developing a new member of a structurally related class of drugs should monitor clinical reports on other members of that class. FDA's experience is that sponsors frequently do report to FDA significant and relevant safety information about such related drugs, and FDA strongly encourages continued reporting of this information to FDA in information amendments or annual reports.

Reporting Time Frames

83. FDA received a considerable number of comments concerning the proposed time frames for reporting IND safety reports. The proposal would have required the sponsor to submit a safety report to FDA no later than 3 working days after receiving information on a fatal or life-threatening experience, and no later than 10 working days after receiving information on any other serious adverse experience. Although most comments agreed on the need for timely reporting of adverse experiences, many contended that the reporting provisions, especially the 3-working-day time frame for fatal and life-threatening experiences, would not give sponsors enough time to review and assess the significance of safety information and would result in the submission of incomplete or misleading information. To remedy these perceived problems, several comments suggested giving sponsors up to 15 days from date of receipt of the initial safety information to make a safety report. Alternatively, other comments recommended that the reporting obligation run from the time that a sponsor received the "essential information" on the experience, or from the time the sponsor determined an event was drug related, rather than from the date of receipt of the initial, perhaps fragmentary, report of the experience. Finally, several comments suggested that safety information derived from foreign experience with investigational drugs should be reported less frequently than other safety information—one comment recommended 3-month intervals—because of the need for translation and because of the greater problems in investigating such experiences.

FDA has carefully considered these comments and has concluded that 3 working days may not be sufficient time to determine whether a death or life-

threatening experience should be reported in a written IND safety report under § 312.32(c). Therefore, FDA has revised the final rule to require that all serious, unexpected adverse drug experiences be reported in a written IND safety report to FDA as soon as possible and in no event later than 10 working days after the sponsor's initial receipt of the information. FDA believes that this change will ensure timely communication of the most important safety information, while giving sponsors a reasonable amount of time to review incoming safety information, to identify reportable information, and to prepare and transmit to FDA complete and accurate safety reports. Although FDA has changed the proposed 3-working-day reporting time for written reports of fatal and life-threatening experiences to 10 working days in order to improve the quality of the reports received (and therefore the likelihood that FDA would have sufficient data to take action, if necessary), FDA emphasizes that such information is required to be submitted "as soon as possible" in order to protect patient safety. Moreover, as described below, sponsors are also required to notify FDA by telephone of an unexpected fatal and life-threatening adverse experience, in advance of the written notification, to provide an early warning that a potential problem exists.

FDA does not agree with those comments that suggest that the reporting obligation should run from the time that the "essential" information on the event is collected as such a provision might unduly delay reporting of vital information. However, FDA understands that 10 working days may not be sufficient time in every case to determine conclusively whether the factors triggering a report under § 312.32(c) are present, i.e., for determining that an adverse event reported to the sponsor is associated with use of the drug and that the event may suggest a significant hazard, contraindication, side effect, or precaution. In those cases in which the sponsor's initial information may not be conclusive, FDA advises the sponsor to err on the side of caution, to submit the preliminary information, and to follow up this initial report with whatever more definitive information is subsequently obtained.

Finally, FDA declines to adopt a different time frame for reporting foreign safety information than the 10-working-day time frame adopted for all other safety information. As the relevance and importance of safety information should usually not depend on the source of the

information, FDA concludes that an exception should not be made for foreign experiences.

84. The final rule requires the sponsor to report a serious and unexpected adverse experience if the experience is "associated with the use of the drug." The proposal defined this phrase to mean that "there is a reasonable possibility that the event may have been caused by the drug." One comment suggested that requiring a sponsor to determine whether an event was possibly caused by the drug introduced a new concept to adverse reaction reporting. Although supporting the concept, the comment suggested that a determination about diverse event causality would require more time than the proposal allowed.

FDA rejects this comment as it believes that 10 working days allowed under this final rule should generally be adequate time to make the required determination. Moreover, FDA does not regard the cited requirement as representing a significant departure from current requirements. Under the current regulation, the sponsor is required to report "any finding associated with the use of the drug that may suggest significant hazards, contraindications, side effects, and precautions pertinent to safety . . ." Implicit in this requirement is an expectation that the sponsor will report events that the sponsor believes may have been caused by the drug. The revision simply makes this expectation explicit. To the extent that assessing the causation of an adverse experience is considered a close call, FDA advises the sponsor to err on the side of reporting.

Telephone Call Requirement

85. A number of comments objected to the proposed requirement that sponsors transmit each IND safety report by telephone at the same time as a written safety report is submitted. Comments criticized the requirements as being unnecessarily burdensome on both FDA and sponsors. Several objected specifically to the proposed requirement that the sponsor contact each investigator by phone, one comment noting that there may be over 100 investigators in a single investigation. Another comment argued that telephone notification served no useful purpose because the same information conveyed by telephone would also be concurrently submitted in a written report prominently identified as an "IND safety report."

Those comments that did not urge rescinding the requirements in its entirety recommended scaling it back significantly. One comment suggested

that telephone reporting should be required only when an adverse event is so alarming that the sponsor elects to discontinue the study. Other comments recommended that sponsors not be required to telephone investigators at all, or that the sponsor only be required to telephone investigators concerning the most significant new safety information.

FDA has revised § 312.32(c)(2) to limit the telephone call requirement to adverse experiences that are obtained from the sponsor's own clinical studies that suggest an unexpected fatal or life-threatening experience associated with use of the drug. The information would be required to be relayed by telephone only to the agency unless FDA also requests the sponsor to telephone all investigators. The change should ensure that a sponsor's reporting obligations are no greater than necessary for the timely communication of the most urgent safety information. Because drug-related deaths or life-threatening occurrences during a clinical trial, the change should also keep the amount of information transmitted by telephone to a manageable level.

FDA emphasizes that the 3-day telephone alert is reserved for the most urgent circumstances. Thus, for purposes of this section, the term "life-threatening" means that the patient was, in the view of the investigator, at immediate risk of death from the reaction as it occurred, i.e., it does not include a reaction that, had it occurred in a more serious form, might have caused death. For example, drug-induced hepatitis that resolved without evidence of hepatic failure would not be considered life-threatening in this context even though drug-induced hepatitis can be fatal.

86. Two comments mistakenly interpreted the proposal as requiring IND safety reports for experiences that occur due to the natural course of the disease being treated.

As noted in the proposal, only adverse experiences "associated with the use of the drug" need be reported, i.e., those events for which there is a reasonable possibility that the event may have been caused by the drug. A death due to the natural course of a disease would not meet this criterion and thus would not have to be reported in an IND safety report. Such deaths, however, would be reported in the annual report. See § 312.33(b)(3).

Safety Report Format

87. One comment noted that the proposal did not specify a reporting

format for IND safety reports and suggested that the form used to report experiences with marketed drugs—the Form FDA-1639—be used.

This final rule does not prescribe the use of any specific format for reporting safety information. However, the agency notes that the one page form FDA-1639 is designed primarily as a means to permit individual physicians to make "spontaneous" reports concerning adverse drug reactions in patients under their care. The form is clearly inappropriate for reporting in a safety report information about animal tests. It is also in most cases not an appropriate means of transmitting information about human clinical experience during a clinical investigation, as more extensive information on individual adverse experiences is needed than can ordinarily be included in a one page report. Generally, while the kinds of data entries required in a FDA-1639 report for a marketed drug are also appropriate for reporting adverse experiences in IND safety reports, more detailed reporting is desirable, particularly for reporting clinical adverse experiences from Phase 1 and 2 studies. While FDA does not encourage use of the form, FDA believes the Form FDA-1639 may in some cases be acceptable for submitting IND safety reports about human clinical experiences during Phase 3 studies and would be happy to discuss use of the form with individual sponsors.

IND Study of a Marketed Drug

88. One comment urged that the regulations specify whether, when a marketed drug is used in a clinical study under an IND, an adverse experience associated with use of that drug product should be reported to the division in FDA's Center for Drugs and Biologics which is responsible for monitoring adverse reactions for marketed drugs or to the IND. The comment suggested that the adverse experience should be reported to only one application with appropriate cross-reference filed in the other application.

As a general rule, FDA agrees that adverse experiences associated with use of a drug that is subject to both an investigational new drug application and a marketing application need not be reported to both. Accordingly, the agency has in this final rule limited IND safety reporting for clinical studies of marketed drugs to those adverse experiences associated with the clinical study itself. Adverse experiences that originate from outside the clinical study (including, for example, "spontaneous" reports submitted to the drug firm by individual practitioners) need not be

reported to the IND file provided such experiences are reported to the marketing application file in accordance with the applicable NDA regulations (21 CFR 314.80).

Followup Reports

89. Several comments addressed the issue of followup reports. One comment, noting that the regulation would require the sponsor to investigate all safety information received by it, asked FDA to clarify what level or degree of investigation would be required for various sources of safety information including, for example, clinical experiences in studies conducted under the IND, reports from the scientific literature, and reports on foreign experiences with the drug.

Regardless of the source of the safety information, FDA expects a sponsor to conduct as thorough an investigation as is feasible to interpret the adverse experience that is the basis for the initial safety report. Of course, some initial reports will require more followup than others. For example, reports of clinical experience in the sponsor's own IND studies or reports of formal clinical trials from the scientific literature might be sufficiently complete in themselves to require little, if any, followup. In contrast, a literature report of an adverse experience that does not tie the experience to an individual patient may require substantial followup. Reports of adverse experiences from foreign marketing experience may be sketchy or even uninterpretable, and a sponsor may be unable to obtain further information. Thus, the extent of followup will depend on the source of the safety information, on the amount of information already reported, and on the potential for obtaining additional useful information through diligent effort.

90. One comment urged FDA to require followup reports to be submitted within 60 days of the initial report (unless a shorter period is required by the agency for a specific adverse experience on grounds of safety), rather than "promptly" as had been proposed. Two comments suggested that the final rule be amended to require the submission of followup reports to IND safety reports "if needed."

Under the final rule, a sponsor is required to investigate all safety information received by it. Ordinarily, these investigations will not be completed within the time limit prescribed for the IND safety report. However, if such investigations are completed within the time frame prescribed, the sponsor should indicate this fact in the IND safety report. No further followup report would then be

required. With respect to the suggested time period for the submission of followup reports to an IND safety report, FDA does not believe it should prescribe any specific time period, given the variety of experiences that may require followup. Therefore, the final rule will remain as proposed.

91. With respect to the provision requiring prompt reporting of "relevant information" in followup reports to an IND safety report, one comment asked FDA to clarify the term "relevant."

Determining the relevance of information is invariably a matter of judgment. In this case, relevant information is information that explains or clarifies the circumstances of the reported adverse experience. For example, each followup might include reports of autopsy findings or reports of the results of additional blood tests. FDA will provide additional guidance on followup on request.

91a. Finally, FDA has added a provision stating that a safety report submitted in accordance with these regulations does not necessarily reflect a conclusion by either the sponsor or FDA that the report constitutes an admission that the drug caused or contributed to an adverse experience. This "disclaimer" provision parallels similar provisions adopted in the NDA Rewrite (50 FR 7452; February 22, 1985) and in the medical device reporting regulation (49 FR 48272; December 12, 1984). The disclaimer provision was adopted in response to comments expressing concern about the legal liability consequences of reporting possible adverse experiences. FDA advises, as it has done previously, that although FDA does not intend for such a report to be viewed as an admission of liability, whether a court will treat a submission to FDA as an admission will depend on factors outside of the agency's control, such as the contents of the report.

Annual Reports (§ 312.33)

92. A number of comments asked that the agency give more detailed guidance on what information should be included in the annual report of an investigation's progress. In addition, comments were interested in knowing whether specifically identified items of information should be submitted in the annual report or in some other submission to the agency. For example, one comment, noting that there was no explicit mention in the annual report section regarding submission of reports from the scientific literature, asked whether such information should be reported in annual reports, safety

reports, or both. Along similar lines, several comments asked whether information on animal studies should be submitted in information amendments or in annual reports. Finally, one comment contended that the proposed annual report requirement for summaries of the previous year's clinical and nonclinical investigations was "unnecessary and burdensome," arguing that by the time the annual report was due such information would already have been reported to FDA in information amendments or other submissions.

FDA has carefully considered these comments and concludes that the submission requirements for annual reports, which are expressed in very general terms in the proposed rule, should be identified in the final rule in more detail. These changes, which are outlined below, should significantly increase the usefulness of these reports in providing both sponsors and FDA with insight into the status and progress of studies. The changes will also provide guidance to sponsors in determining whether information obtained during the course of the investigation should be submitted in information amendments or safety reports rather than in the annual report.

As proposed, § 312.33(a) called for a brief summary of the status of each of the clinical studies conducted (both those in progress and completed) during the past year, but did not specify the contents of such reports. To clarify this requirement, FDA has revised § 312.33 to require the sponsor to submit: (1) Brief "identifier" information for each study, and (2) a brief numerical analysis of patient exposure to the investigational drug in that study, i.e., the number of subjects planned for inclusion in the study, the number whose participation in the study was completed as planned, and the number who dropped out. The final rule also requires a brief description of the study outcome or interim results for each study—on a study-by-study basis—for which results are available. This should be a concise, one or two sentence statement of study results. For example, if the study made some important finding about pharmacokinetics, that should be so indicated. Likewise, if a placebo-controlled study distinguished or failed to distinguish between the investigational drug and the placebo, that too should be so stated.

In addition to these clarifications of the "status report" elements of the annual report, the final rule also elaborates on the proposed provision in § 312.33(b) requiring a brief summary of information obtained during the

previous year's investigations. This section serves as a means to bring together data from individual studies and briefly communicate what was learned during the past year about the investigational drug's safety and effectiveness. The final rule specifically identifies five pieces of information to be included in the annual report relating to the clinical experience with the drug: (1) A summary showing the most frequent and most serious adverse experiences by body system; (2) a summary of the past year's safety reports; (3) a list of subjects who died during the past year; (4) a list of subjects who dropped out of clinical investigations during the past year; and (5) a brief description of what, if anything, was obtained that is pertinent to an understanding of the drug's actions. Also, this provision requires a list of preclinical studies (including animal studies) completed or in progress during the past year and a summary of major preclinical findings. Finally, the sponsor is expected to submit a summary of any significant manufacturing or microbiological changes made during the past year.

The agency believes that there should be little overlap between the information submitted by the sponsor in information amendments, protocol amendments, or safety reports and information submitted in the annual report. As noted above, FDA expects annual reports in general to contain brief information summing up what was learned about the investigational drug during the past year. Annual reports thus provide a periodic overview of the investigation's progress. In contrast, amendment and safety reports contain specific information needed by the agency in determining whether to continue to allow the study to proceed.

93. Several comments recommended that the required lists of deaths and drop-outs include only deaths and drop-outs related to the safety of the investigational drug. One comment contended that to include nonsafety related deaths and drop-outs would require FDA's reviewers to sort through potentially long lists of subjects and extract from those the cases related to safety, and that this sorting process would create considerable work for both the sponsor and the agency without offsetting benefits. The comment recommended confining the lists of deaths and drop-outs to those subjects who suffered a drug-related adverse reaction and who were not previously identified in safety reports to FDA. Thus, according to the comment, every drug-related reaction would be

submitted to FDA in either a safety report or an annual report.

Because of the difficulty of assessing the meaning of single adverse experiences—of determining, for example, whether the death of a subject in a study of a cardiovascular drug is due to the drug itself or to the natural course of the disease being treated—FDA believes it is important periodically to aggregate all such experiences, whether or not the individual events are thought to be drug related, for review and analysis. Such grouping may show an increased incidence of an adverse experience or other problem that would not be readily ascertainable in a review of single, discrete adverse experiences. Therefore, FDA believes that the list of deaths and drop-outs in the annual report should include all deaths or drop-outs, whether or not thought by the sponsor to be drug related.

94. Several comments objected to the requirement that the annual report contain an updated general investigational plan for the following year. One comment questioned the value of submitting in each annual report a wholly new description of the general investigational plan for the coming year. The comment claimed that it is difficult, if not impossible, to schedule clinical trials with precision and that artificial time frames like the "coming year" are, therefore, inappropriate. Another comment suggested that the requirement would increase the sponsor's burden in preparing annual reports and increase the amount of material that FDA must review. The comment recommended that the provision be revised to require only a description of significant changes in the investigational plan not covered by previously submitted amendments or other sections of the annual report.

As noted in the discussion of comments on the general investigational plan in paragraphs 39 through 41, FDA does not expect the general investigational plan to be a detailed description of future clinical studies, but rather a very brief summary of plans for clinical studies for the following year. As noted earlier, the purpose of the plan is simply to place individual studies within a larger context so that FDA reviewers are not operating in a vacuum. Moreover, the provision does not obligate the sponsor to invest resources into formulating plans that are not otherwise available; if at the time the sponsor submits the annual report, plans for the following year are not yet formulated, the sponsor need only so state in the submission. For these reasons, FDA believes the requirement

does not represent a significant burden and should be retained as proposed.

95. One comment asked whether, if the general investigational plan for the coming year is unchanged, the plan must be resubmitted.

FDA advises that if the plan for the following year is unchanged, the sponsor may simply refer to the previously submitted plan.

96. One comment asked whether the requirement for a brief summary of significant foreign marketing developments with the drug during the past year applied to the experience of other firms that may be marketing the same dosage form of the drug, or applied only to the sponsor's experience.

Reports of regulatory actions taken by foreign drug licensing authorities—such as license refusals, or withdrawals from the market for safety reasons—frequently signal potential problems with an investigational drug. As the relevance and significance of this information would usually not depend on the identity of the company marketing the drug, FDA believes a sponsor should report to FDA all significant foreign regulatory actions taken, whether or not the action was taken with respect to the sponsor's own drug. Finally, FDA would expect a sponsor to report significant actions taken not only with respect to the specific dosage form under study, but also with respect to other dosage forms of the drug, since such information may also be extremely valuable.

97. On its own initiative, FDA has revised § 312.33 to specify that the sponsor is required to submit the first annual report no later than 60 days after the anniversary date of the initial IND submission. FDA believes this provides needed guidance on the proper timing of annual reports and represents a reasonable time frame within which to prepare and submit such reports.

Identification of Patients

98. One comment expressed concern that the proposed regulation would not protect subjects' rights of privacy. The comment noted that several sections of the proposal would require the submission of a list of "deaths and drop-outs" and interpreted this to require the sponsor to identify subjects by name. The comment contended that the sponsor should not be expected to have this information in its files, and that, moreover, many sponsors go to great lengths to delete subject names from files. The comment contended that the regulation should permit the use of other identifiers, which could then be used in conjunction with the investigator's records to identify a subject by name.

As noted in the NDA Rewrite final rule (§ 312.80(h)), FDA does not expect a sponsor to maintain in its records the names and addresses of individual subjects. In reporting deaths and drop-outs, moreover, to protect subject confidentiality, sponsors should identify subjects by initials or some other sort of coding, rather than listing subjects by name and address. However, sponsors and/or participating investigators are still required to retain sufficient information about subjects to permit FDA to find the name and address of a subject should the need to do so arise.

Treatment Use of an Investigational New Drug (Proposed § 312.34)

98a. Elsewhere in this issue of the *Federal Register*, FDA is reproposing new rules governing treatment use of investigational new drugs. Comments received on this issue are addressed in that reproposal. Because there are no existing regulations governing treatment use, § 312.34 has been held in reserve.

Emergency Use of an Investigational New Drug (§ 312.36)

99. One comment from a professional medical association complained that the proposal did not specify the appropriate procedures for obtaining an investigational drug in an emergency and urged that the final rule include detailed guidance for the benefit of individual physicians. Another comment contended that if an emergency need for an investigational drug arises after normal working hours or on a week-end or holiday, a requirement that no emergency shipment may be made without FDA authorization could possibly delay initiation of vitally important therapy. This comment recommended that the provision be revised to permit emergency shipment of a drug without FDA authorization if: (1) No responsible agency official can be reached by telephone; (2) the sponsor obtains the authorization of the chairman of an appropriate reviewing IRB; and (3) FDA is notified of the shipment by telephone as soon thereafter as is practicable.

FDA advises that, even when a situation arises that in the judgment of a treating physician calls for the emergency use of an investigational drug, an IND is still necessary. The physician's first step should be to contact the manufacturer of the drug and determine whether the physician may be added as an investigator under the manufacturer's IND. Should the company elect not to add the physician to its IND, the physician should then contact the agency directly.

When contacting the agency, the physician will be placed in contact with an FDA medical officer familiar with the drug who will review the proposed circumstances for use. If the medical officer is satisfied that emergency use of the drug is justified, the medical officer may authorize its shipment and use in advance of any formal written submission to the agency.

Because the procedures governing "emergency IND's" may change from time to time, FDA has not codified the details of current practices into this final rule. However, the final rule does identify the specific review office to contact to get the process in motion. Also, FDA has prepared an informational sheet that describes in some detail the procedures to be followed to obtain emergency authorization to use an investigational drug. The informational sheet also describes an investigator's responsibilities in an emergency with respect to informed consent and IRB review requirements. This informational sheet is available from the Food and Drug Administration, Office of the Associate Commissioner for Health Affairs (HFY-20), 5600 Fishers Lane, Rockville, MD 20857 (301-443-6143).

Requests for emergency authorization that are received after normal duty hours are handled like those received during the working day, except that in such cases the initial contact will be FDA's duty officer or the agency answering service rather than the appropriate review office. Because this procedure has worked well, and has not, to the agency's knowledge, materially delayed shipment of urgently needed drugs, FDA does not believe there is a need for an alternative procedure.

100. One comment perceived an inconsistency between the emergency use provisions of the IND regulations and the provisions in the IRB regulations (21 CFR 56.104) governing the proper role of the IRB with respect to the emergency use of test articles. The IRB regulations permit the emergency use of an investigational drug without prior IRB review and approval provided that the IRB is notified of such use within 5 working days. This comment concluded that this provision of the IRB regulation represented sound policy and should override any conflicting sections of the IND regulations.

This comment erroneously characterized this provision of the IRB regulations as exhausting all FDA regulation of emergency use of investigational drugs. However, IRB review requirements are supplemental to the requirements for an IND. As noted

above, when a physician wants to obtain authorization to use an unmarketed investigational drug in an emergency, an IND is still required.

Withdrawal of an IND (§ 312.38)

101. Proposed § 312.38 sets forth procedures for withdrawing an IND by a sponsor. Two comments recommended that the final rule provide that IND withdrawal not result in the public availability of confidential data submitted by the sponsor. One comment contended that the act of withdrawing an IND, in itself, should not trigger the release of confidential data, since that data may have proprietary value with respect to related compounds or other possible indications for that same compound.

The public availability of all data and information in an IND for a new drug or antibiotic drug will be governed by § 314.430, which describes the rules for disclosing information submitted in a marketing application under Part 314. The rules for public disclosure of information for biological investigational drugs are set forth in 21 CFR 601.50 and 601.51. In general, these rules hinge public disclosure on whether the information requested is trade secret or confidential commercial or financial information, and not on whether the application is formally pending with the agency. Thus, the fact that an IND has been withdrawn is not, in itself, determinative of the public availability of information in the IND file.

102. One comment suggested revising § 312.38(b) to make clear the sponsor's responsibilities for disposing of an investigational drug once the investigation is ended.

The agency has added a new section (§ 312.59) to describe a sponsor's responsibilities for disposing of an investigational drug. Under that section, sponsors are required to assure the return or other authorized disposition of all unused supplies of an investigational drug whenever an investigator ends his or her participation in the investigation, or the investigation is terminated.

Administrative Actions

General Requirements for Use of an Investigational New Drug In a Clinical Investigation (§ 312.40)

103. One comment objected to retaining the system under which an IND goes into effect 30 days after FDA receives the IND unless FDA notifies the sponsors that the investigations covered by the IND may not begin. The comment acknowledged the need for expeditious review of investigational applications, but expressed concern that during

substantial portions of the 30-day period the application may not actually be available for review by FDA's scientific reviewers because of the time needed to route the IND to the scientific reviewers. The comment recommended that, in light of this "delay," the 30-day period should be deemed to begin from the time that the application has actually been transmitted to the responsible reviewing officials.

Under longstanding practice, agency reviewers have had 30 days from date of receipt of the IND to review the submission. Agency reviewers are asked during this period to decide whether the information submitted in the IND supports initiation of the proposed clinical investigations. Only rarely has the agency found the 30-day period, which period includes the administrative time taken up in routing a submission from the file room that initially receives the IND to the designated scientific review team members, insufficient to conduct an adequate initial review. In those rare cases, the agency has invariably obtained the sponsor's agreement to delay its proposed studies pending completion of the agency review. FDA believes this system has worked satisfactorily and should not be changed.

Clinical Holds and Requests for Modification (§ 312.42)

104. Several comments supported codifying clinical hold procedures in the regulations. However, a number of comments objected to the proposed criteria for imposing a clinical hold and also to the proposed procedures under which clinical holds would be implemented. These specific objections are discussed in detail below.

105. One comment suggested that the standard for a clinical hold based on a finding that the investigator brochure is "misleading, erroneous, or materially incomplete" (proposed § 312.42(b)(1)(iii)) be reworded to require a finding that "the investigator brochure is materially misleading, erroneous, or incomplete."

The agency believes that any information in an investigator brochure that is "misleading" or "erroneous" is presumptively "material" in terms of significance, and therefore the explicit qualifier suggested by the comment is unnecessary. However, the "incompleteness" of an investigator brochure may be of minimal significance and, therefore, an insufficient basis for imposing a hold without a further finding that the deficiency is material with respect to the function of the brochure. Therefore, the agency

concludes that this provision should be retained as proposed.

106. Under proposed § 312.42(b)(2)(ii), a clinical hold may be imposed on a Phase 2 or 3 study where "the plan or protocol for investigation is clearly deficient in design to meet its stated objectives." One comment objected to the omission of this grounds for clinical hold from the criteria applicable to Phase 1 studies. The comment contended that the safety of a study cannot be evaluated without a critical inquiry into its scientific merits and concluded that it would be difficult to assure subject safety absent a carefully drawn research protocol. In contrast, several comments objected to the retention of this criteria for studies in any phase. These comments contended that FDA's mandate does not extend to stopping a clinical investigation based solely on the agency's views of the scientific deficiencies of the investigation. Finally, one comment contended that it is inappropriate to interrupt the course of a planned clinical investigation, which may involve the investment of significant amounts of time and financial resources, unless there is a well-founded concern for the safety of study subjects.

As discussed in paragraph 31 above, FDA has both the authority and responsibility to establish conditions, including a review of study design, to ensure that a study that is conducted to develop evidence of a drug's safety and effectiveness is designed to achieve its objectives. Review of study design may prevent unnecessary mistakes, may assure the adequacy of a study, and may otherwise increase the likelihood that completion of the study will generate the kind of data needed to make a final determination about the drug's safety and effectiveness.

FDA is sensitive to the potential costs and disruptiveness of a clinical hold, and will not impose a hold because of design problems unless it finds the study to be "clearly deficient in design to meet its stated objectives." This intentionally places a substantial burden on FDA to show that a design defect is critical with respect to the purposes of the study. The criterion is a guarantee that FDA will not casually impose clinical holds for trivial or easily correctable design problems. When this standard is met, however, imposing a clinical hold will preclude exposure of human subjects to risks in an investigation that FDA concludes would ultimately have no scientific or regulatory value. It will also save substantial drug development time, in the long run, by preventing

continuation of a study that could not possibly support marketing approval.

The agency discussed previously its reasons for "narrowing" the focus of Phase 1 review to matters of subject safety alone. As noted in that discussion, the narrow focus reflects a desire to remove impediments to innovation at this early stage of drug discovery. While the narrower focus may mean that some poorly designed studies will be conducted that would otherwise have been placed on clinical hold, FDA believes the likelihood of this happening is slight, and that the safety considerations arising from such an occurrence are not significant in that FDA will still have reviewed the study for subject safety generally. On balance, therefore, FDA believes it appropriate to defer to sponsors on matters of Phase 1 study design.

FDA notes that a number of potentially safety-related criteria are listed as bases for terminations, but are not listed as bases for clinical holds. Thus, for example, while § 312.44(b)(1)(iii) authorizes FDA to terminate a study on finding that the methods, facilities, and controls used for manufacturing the drug "are inadequate to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for subject safety," this factor is not listed among the bases for clinical holds under § 312.42(b). The omission of such specific criteria from the listed criteria for clinical holds is not intended to suggest that they would not be a basis for a clinical hold, if the particular deficiency posed an unreasonable and significant risk of illness and injury to human subjects. To the contrary, FDA would view the deficiency to be a proper basis for a clinical hold under the provisions of § 312.42(b) (1)(i) and (2)(i).

107. Several comments urged the creation of additional procedural safeguards and a better appeals mechanism relating to the imposition of clinical holds. One comment claimed that the promise in proposed § 312.42(c) that FDA will, before issuing the clinical hold order, attempt to discuss and satisfactorily resolve the matter with the sponsor, can be interpreted to mean anything from a casual attempt at telephone communication to a requirement for a formal meeting. Given the potential significance of a clinical hold for a sponsor's drug development plans, the comment urged that the sponsor be given 48-hour notice of a hold imposed for safety reasons and longer notice for holds imposed for nonsafety reasons. In either case, the comment urged that a sponsor be given

the right to meet or talk by telephone with the responsible reviewing official before the hold goes into effect. Another comment, while conceding that it may be appropriate to impose an immediately effective hold where the safety and rights of human subjects are at stake, recommended that in all other cases a clinical hold not become effective until the sponsor has exhausted all appeals rights including, ultimately, the right to a regulatory hearing before the agency under Part 16.

The procedures governing the imposition of clinical holds are tailored to the needs of a regulatory process that gives reviewers little time to decide whether proposed studies should begin or ongoing studies continue: studies under an IND may begin 30 days after FDA is given notice by the sponsor, and these same studies, once begun, may be significantly changed in direction or scope under protocol amendments without any advance notice to FDA. The relative informality and flexibility of the clinical hold procedures, criticized by the comments, are thus, in the agency's view, dictated by the nature of the process.

While the agency is committed to making a good faith attempt to discuss and satisfactorily resolve deficiencies in an IND before considering the need to impose a clinical hold, it does not believe that it is obligated to establish procedural safeguards of the types suggested by the comments. The nature of the agency contact with sponsors will depend on the imminence of hazard to human subjects, on the availability of key agency and sponsor personnel, and on a variety of other factors.

For similar reasons, FDA believes that it cannot in the abstract specify the extent of notice that can appropriately be given a sponsor before making a hold effective.

108. Several comments urged that the clinical hold provisions make clear the agency's obligation to explain the reasons for a hold when it is imposed.

Agency practice has been to explain briefly the basis for a clinical hold when it is imposed, and to follow up this initial communication with a written explanation of the agency's action. FDA has revised the final rule to reflect this practice.

109. One comment urged that the procedures governing the resumption of a clinical investigation placed on clinical hold be revised to permit the order rescinding the hold to be made by or on behalf of the Division Director. (The proposal provided that such rescission order could only be made by the Division Director.) The comment

also recommended that the clinical hold procedures specifically permit FDA to authorize resumption of a study by telephone or by other means of rapid communication.

FDA agrees with these suggestions and has revised the regulation accordingly.

110. Proposed § 312.45(a) would give the agency the authority to convert an IND to inactive status if all clinical investigations covered by the IND remain on hold for 1 year or more. Several comments recommended revising this to state that any IND on clinical hold will be placed on inactive status only in the event that the clinical hold is no longer contested by the sponsor of the investigation.

FDA believes that as a matter of administrative efficiency—to "clear the books"—it is appropriate that the agency retain the authority to place an IND on inactive status if all studies under the IND have been on clinical hold for at least 1 year. The 1 year between imposition of the clinical hold and transfer to inactive status should generally be more than sufficient time to raise and attempt resolution of the deficiencies that prompted the agency to place the studies on clinical hold.

It should be noted that inactivation of a study under the circumstances described by the comment is not automatic. Under § 312.45(a), if FDA seeks to place a study on inactive status, it must give the sponsor notice of the proposed action and an opportunity to respond as to why the IND should remain active. The fact that issues surrounding a clinical hold order remain under dispute may be a legitimate basis for a sponsor request to continue an investigation as "active."

111. One comment urged that FDA elaborate on the scope of a clinical hold. The comment claimed that it would not be reasonable to halt a study with six investigators when only one had been found to be inadequately qualified to participate in it.

If FDA finds that only one of several investigators named in an IND is not qualified to conduct the investigation, the clinical hold order would ordinarily be limited to the study conducted by that investigator. This concept is noted in § 312.42(a) of this final rule, which states that the clinical hold order may apply to one or more of the investigations covered by an IND.

To ensure that the sponsor is informed of the precise limits of the clinical hold order, FDA has revised the final rule to require the Division Director (or the Director's designee) to specify in the

initial communication to the sponsor the studies to which the hold applies.

As proposed, the clinical hold procedures (§ 312.42) gave FDA 15 days from the date of imposition of a clinical hold to provide the sponsor with a written explanation of the basis for the action. On reconsideration, FDA concludes that 15 days may not allow the agency sufficient time to provide the sponsor with a complete written explanation of the basis for its action. Accordingly, § 312.42(d) has been revised to require the agency to provide a written explanation "As soon as possible, and in any event within 30 days of the imposition of the clinical hold."

Termination (§ 312.44)

112. Under proposed § 312.44(b)(1)(iv), FDA would be able to terminate an investigation on a finding that clinical investigations are not being conducted in accordance with the plan or protocol submitted. One comment suggested that minor departures from these protocols and plans should not be the basis for terminating an IND, and recommended conditioning such actions on a finding that the investigations are being conducted in a manner "substantially different" from the plan or protocol submitted.

The agency agrees and has revised the final rule accordingly.

113. Under § 312.44(b)(2)(ii), FDA may terminate a Phase 2 or 3 investigation if it finds that the investigational plan is not reasonable as a bona fide plan to determine whether or not the drug is safe and effective for use. One comment urged that this standard not be used to prevent or preclude pilot studies or exploratory research that might not, taken alone, be satisfactory to establish safety and effectiveness. Another comment objected to the standard on the grounds that it would permit FDA to prevent clinical investigations "merely on the basis of the agency's opinion as to the value of what FDA anticipates will be their results." This comment urged that a determination under this provision require, in addition, a finding that a continuation of the investigation would subject human subjects to an unreasonable and significant risk of illness or injury.

Proposed § 312.44(b)(2)(ii) was intended to give FDA grounds for terminating an investigation that was not directed, overall, at evaluating safety and effectiveness of the drug. The criterion would not provide grounds for terminating an investigation simply because one or another study was considered inadequate. A bona fide investigational approach may well

include pilot studies, open safety studies, and other studies that would not, by themselves, establish a drug's safety and effectiveness.

114. As proposed, § 312.44(b)(2)(iii) would authorize FDA to terminate a study on finding that "There is convincing evidence that the drug is effective for the purpose for which it is being investigated." This provision has been corrected in the final rule to read "There is convincing evidence that the drug is not effective for the purpose for which it is being investigated."

115. Under proposed § 312.44(d), FDA could immediately terminate an IND on finding that the continuation would present a significant danger to the public health. One comment suggested revising this language to condition an immediate termination on a finding of an "unreasonable, direct, and substantial danger to the health of individuals."

The agency believes that the immediate termination procedure should focus more directly on the health of individuals and therefore has revised § 312.44(d) in this final rule to condition such terminations on a finding of "an immediate and substantial danger to the health of individuals."

Inactive Status (§ 312.45)

116. Several comments objected to the provisions under which FDA could terminate an IND that has been on inactive status for 5 years. One comment suggested that the prospect of termination eliminates the principal value of inactive status to sponsors and will discourage them from seeking it.

FDA believes that the provision for terminating IND's that have been on inactive status for 5 years or more is reasonable to permit the agency to focus its resources upon clinical investigations that are actually being conducted and to keep government records current. Moreover, the termination procedure in § 312.44 is not automatic: under the procedure, the sponsor has an opportunity to respond to an agency proposal to terminate an IND with an explanation of why it should continue on inactive status. Finally, FDA does not believe sponsors will be adversely affected by termination of an IND that has long been inactive, both because the termination of an IND does not preclude a sponsor from proposing new studies in the future under another IND, and because the agency has, in the NDA Rewrite final rule, amended § 314.430 governing the disclosure of information in a terminated IND to assure the continued confidentiality of trade secret, confidential commercial, and financial information.

Meetings (§ 312.47)

117. Comments agreed with FDA's view that meetings between a sponsor and the agency are frequently useful in resolving questions and issues raised during the course of a clinical investigation. Noting, however, that under current practice there is sometimes a delay of several months in scheduling meetings, comments urged that meetings be held promptly after a request is submitted. Also, one comment urged that advance written information in support of a meeting should be kept to a minimum, and that requests for such information should balance the sponsor's costs in preparing the material against the expected results.

The agency agrees that sponsors should not be asked to prepare and submit more information in advance of a meeting than is needed to ensure a productive exchange of views at the meeting. This principle does not mean, however, that the amount of advance information can or should always be kept to a bare minimum. To the contrary, the successful conclusion of many meetings may demand a considerable investment of time and resources in developing background information. This is especially true for meetings such as an end-of-Phase 2 conference, whose primary purpose is to evaluate the adequacy and significance of data developed by the sponsor.

FDA also agrees that meetings are most useful if held promptly after requests for them are submitted and after the necessary advance information has been submitted. The agency will make every effort to schedule such meetings as early as is feasible and to the extent that agency resources permit.

118. One comment requested that the final regulation specifically authorize and encourage "pre-IND" meetings, i.e., meetings between sponsors and FDA prior to the actual submission of an IND. The comment contended that such meetings are often needed to answer questions about technical requirements for an IND and may be essential for planning a clinical study.

The final rule identifies two specific points during the drug development process when meetings between a sponsor and FDA can be particularly useful and productive: (a) at the end of Phase 2; and (b) at the end of Phase 3, but prior to submission of a marketing application. FDA has codified those two meetings because they are exceedingly valuable to both agency reviewers and sponsors and because they are useful for a vast majority of IND's. Although "pre-IND" meetings may be useful for a

particular case, FDA does not believe their utility will be so generalized as to warrant separate codification. The agency notes, however, that individual sponsors may request such meetings under § 312.47(a) as the need may arise. FDA encourages such meetings to the extent that they aid in the evaluation of the drug and associated scientific issues.

119. Two comments contended that many NDA approvals are delayed by questions and concerns about manufacturing and control information. The comments recommended that FDA expand the list of subjects for "pre-NDA" meetings to include these kinds of technical issues.

FDA has no objection to sponsors raising for discussion at "pre-NDA" meetings technical problems relating to the chemistry, manufacturing, and control segment of the marketing application. FDA has revised the final rule to make clearer FDA's willingness to discuss these and other technical matters at such meetings.

Sponsors should also be reminded that the NDA final rule (§ 314.50(d)(1)(iv)) has established a procedure specifically authorizing the early submission and review of chemistry, manufacturing, and control information. Under this procedure, applicants may submit the chemistry, manufacturing, and control part of the marketing application 90 to 120 days in advance of the rest of the application. This procedure may frequently be superior to the "pre-NDA" meeting as a means of resolving the highly technical issues involved.

Dispute Resolution (312.48)

120. The IND Rewrite proposal contained a new formal appeals process for resolving disputes between FDA and sponsors. The appeals process was first outlined in the proposed NDA Rewrite and was more fully described in a publicly available FDA Staff Manual Guide 4820.5. Under that process, drug firms could appeal requests by agency employees for specific additional studies or information, requests to modify or delay a study, or unfavorable agency responses to sponsors' requests for waivers or special technical approaches to scientific problems. The procedure became available for use for both IND's and NDA's through issuance of the Staff Manual Guide noted above.

FDA first received adverse comments on this appeals procedure in the NDA Rewrite rulemaking, and these objections were reiterated in the IND Rewrite rulemaking. The comments suggested that the appeals process was, on the one hand, too complex for resolving minor administrative and

procedural disputes, and, on the other hand, too inflexible to handle efficiently major scientific and medical disputes, which, according to the comments, should be referable as a matter of right to one of FDA's standing advisory committees.

FDA in general agreed with these observations about the shortcomings of the formal appeals mechanism. The agency's view of the deficiencies of the process was underlined by the fact that the appeals process was rarely used successfully during the more than 1 year it was effective. For these reasons, in issuing the NDA Rewrite final rule, FDA abandoned the formal process in favor of a more comprehensive approach to dispute resolution. This approach entailed establishing a range of procedural alternatives, each tailored to a specific kind of dispute, and then referring sponsors to whichever of the available procedural mechanisms was best suited to the particular matter under discussion. FDA now concludes that a comparable dispute resolution mechanism should be adopted for the IND process and § 312.48 of this final rule has been revised accordingly.

There are three chief components of this new appeals process: (1) The use of an ombudsman to deal with administrative and procedural problems; (2) the codification of an informal process for resolving scientific disputes; and (3) the increased use of outside scientific advisers, when feasible and appropriate.

First, the final rule encourages sponsors to seek the help of a designated "ombudsman" to resolve administrative and procedural disputes arising during the course of an investigation. The function of the ombudsman is to investigate the facts and to facilitate a timely and equitable resolution of the issue. Appropriate issues to raise with the ombudsman include resolving difficulties in scheduling meetings, obtaining timely replies to inquiries, and obtaining timely completion of pending reviews. Details on the role of the ombudsman are set forth in a publicly available FDA Staff Manual Guide 4820.7. (Other elements of the new dispute resolution mechanism are described in the revised FDA Staff Manual Guide, "Appeals Process: Resolving Scientific Disputes Over Drug Applications" (CDB 4820.5).)

The second component of the dispute resolution mechanism emphasizes the value of informal communications between sponsors and FDA as the best means of resolving important technical and scientific issues quickly and amicably. If scientific or medical disputes arise, the final rule provides

that applicants should first discuss the matter directly with the responsible reviewing officials. If these discussions do not resolve the matter, applicants may request an informal meeting with the appropriate reviewers and supervisors. Alternatively, disputes may be appropriately discussed at a more formal, "pre-NDA" or "end-of-Phase 2" meeting.

Finally, the new procedures recognize the advantages of utilizing the advice of outside scientific experts in the dispute resolution process, where it is practicable and feasible to do so. Section 312.48(c)(3) of the final rule therefore provides that, in requesting a meeting with the agency to resolve a scientific or medical dispute, sponsors may suggest that FDA seek the advice of outside experts, in which case FDA may, in its discretion, invite to the meeting one or more of its advisory committee members or other agency consultants, as designated by the agency. The applicant is also free to bring its own consultants.

Section 312.48(c)(3) of the final rule also provides that, for major scientific and medical policy issues not resolved by informal meetings, FDA may on its own initiative refer the matter to one of its standing advisory committees for its consideration and recommendations. Although § 312.48 does not provide the right to advisory committee review requested by some comments, FDA does intend to integrate outside experts more fully into the IND portion of the drug approval process. FDA believes that providing applicants a right to advisory committee review for any disputed issue is impractical from the standpoint of the potential number of controversial issues and the relatively infrequent number of advisory committee meetings. Moreover, utilization of outside advisory committees is committed to the discretion of the agency, and not properly delegated to members of the public. Nonetheless, by involving individual advisory committee members or consultants in the dispute resolution process on a more informal basis, FDA believes that the goal of interacting with the scientific community can be achieved without the delays, resources, and scheduling problems associated with full advisory committee involvement.

Responsibilities of Clinical Investigators and Sponsors

122. As noted in the introduction, the proposed IND Rewrite was issued on the assumption that proposed Part 52 governing the obligations of sponsors and monitors and proposed Part 54 governing the obligation of clinical

investigations would be adopted as final rules before, or at the same time as, this final rule. As noted, because those proposals have not been made final, FDA has retained in new Part 312 most of those obligations of investigators and sponsors in existing Part 312 that were to be transferred to in Parts 52 and 54. While in general, the obligations of sponsors, monitors, and clinical investigators are the same as those set forth in the existing IND regulations, in three areas, FDA is adopting minor changes that relate to provisions first proposed in the September 27, 1977, and August 8, 1978, proposed rules. These areas are: (a) Obligations assigned to contract research organizations; (b) disclosure of study audits conducted by the sponsor; and (c) the standard for disqualifying clinical investigators. These changes apply to investigational new animal drugs as well as new drugs for human use. They will be discussed in turn.

Contract Research Organizations

The agency is adopting certain provisions relating to contract research organizations based on proposed Part 52 (see proposed § 52.5 at 42 FR 49623). A contract research organization is an independent organization that contracts with a sponsor of a clinical investigation to assume one or more obligations of the sponsor for the conduct of a clinical study. Use of contract research organizations has grown increasingly common in the United States. Adoption of these provisions represents a regulatory acknowledgment of this common practice.

The final rule: (1) Defines the term "contract research organization" (§ 312.3); (2) authorizes a sponsor to transfer any or all of the sponsor's obligations for the conduct of the clinical study to a contract research organization (§ 312.52(a)); (3) requires that the sponsor keep a written statement that outlines what obligations have been so transferred (§ 312.52(a)); and (4) describes the responsibilities of both the sponsor and the contract research organization, once having made such a transfer (§ 312.52 (a) and (b)). In addition, the final rule requires that the sponsor disclose in the IND whether any obligations have been transferred to a contract research organization, and, if so, that the sponsor list the obligations transferred. Finally, 21 CFR Part 314 is amended by adding new § 314.50(d)(5)(x) to conform Part 314 to Part 312 with respect to contract research organizations.

The agency is adopting identical changes concerning contract research organizations in the investigational new

animal drug (INAD) and new animal drug application (NADA) regulations.

A number of persons commented on the provisions pertaining to contract research organizations when proposed Part 52 was issued. A summary of these comments and the agency's responses follow:

i. Several comments objected to the proposed requirements that obligations transferred to a contract research organization be specifically described, stating that a general transfer of all obligations should be allowed. These comments argued that because a sponsor is often unable to describe specifically each aspect of an obligation transferred before a study begins, it would be unrealistic to have those obligations that were not specifically described considered not to have been transferred at all.

FDA agrees that when a sponsor transfers all its responsibility for the conduct of a study, a statement of this general transfer of obligations should be allowed. The regulation has been revised accordingly. Therefore, when a sponsor transfers all obligations regarding the conduct of a clinical study to a contract research organization, the written statement may indicate that a general transfer has been made and need not enumerate the specific obligations transferred. However, in other cases, i.e., when less than all obligations are transferred, specificity in describing the transfer of obligations of a sponsor to a contract research organization is essential. In such cases, because a contract research organization is required to comply with the specific regulation applicable to any obligations it assumes for a sponsor, a sponsor must be able to set forth specifically each obligation that it expects the contract research organization to assume. The specification of the transferred obligations ensures that the contract research organization knows exactly what its obligations are before beginning a clinical investigation.

While a contract research organization may assume any or all of the sponsor's responsibility for the conduct of a study, it should be emphasized that the transfer does not relieve the sponsor from responsibility for the quality and integrity of any data derived from the investigation that are submitted to FDA.

ii. One comment requested an explicit statement to the effect that if a contract research organization is subjected to administrative action, the sponsor will not also be subject to this same administrative action if the sponsor

complied with all applicable requirements governing the transfer of obligations.

The agency considers such explicit language unnecessary because the written statement identifying what obligations have been transferred will clearly fix the individual sponsor/contract research organization responsibilities. The agency may, therefore, initiate action based upon failure to comply with a regulatory obligation against only the party that has assumed responsibility for, but has not fulfilled, a particular obligation. The agency does not contemplate taking administrative action against a sponsor based solely upon the failure of a contract research organization to perform obligations that have been transferred to it by the sponsor. Sponsors should, therefore, take special care that transferred obligations are described clearly.

iii. One comment asked whether the name of the specific monitor within the contract research organization must be submitted to FDA, along with the name and address of the contract research organization.

The name of the monitor is required to be submitted. See § 312.23(a)(1)(vi) in this final rule.

Disclosure of Study Audits

Proposed Part 52 would have required that a monitor designated by the sponsor visit investigators periodically to, among other things, audit case report forms against individual subject records to assure the accuracy and completeness of the forms (see proposed § 52.20(b) at 42 FR 49623, 49624). While the agency believes that such audits are extremely important, it has concluded that it should not compel such reviews by regulation.

Rather, the agency has concluded that it should only require that a sponsor, in its submission to the agency of a report of a clinical investigation, state whether the investigator's subject records were audited or reviewed in the course of monitoring a clinical investigation. The agency is adding new § 314.50(a)(5)(xi) as a necessary conforming amendment to Part 314. The agency is also making an appropriate change to the NADA regulations by adding a new § 514.1(b)(8)(ix).

As noted above, although FDA has not made the auditing of subject records mandatory in this final rule, FDA concludes that it should know whether such a review has, in fact, been conducted. Knowledge that a sponsor has audited subject records may affect the detail with which FDA conducts its

own inspection of the supporting data. Moreover, in those cases where an agency inspection is not conducted, e.g., in some foreign countries, whether the sponsor has audited the study is an important factor to be considered in evaluating the study. Thus, FDA believes that disclosure of which studies have been audited will significantly improve the efficiency of the agency's clinical investigator inspection program while representing a minimal additional burden on study sponsors.

Disqualification of Clinical Investigators

123. The agency is retaining all the current standards and procedures governing disqualification of clinical investigators, with only one modification. The existing regulations permit the agency to disqualify an investigator on a finding that "the investigator has repeatedly or deliberately failed to comply with the conditions of the exempting regulations *** or has repeatedly or deliberately submitted false information to the sponsor of an investigation and has failed to furnish adequate assurance that the conditions of the exemption will be met ***" (§ 312.1 (c)(2)) (emphasis added). This final rule deletes the provision allowing a clinical investigator to avoid disqualifications through the submission of "adequate assurances" of future compliance.

This action is based on proposed Part 54, which would have similarly limited the grounds for disqualification (see proposed Part 54, Subpart K, at 43 FR 35227). Under the 1978 proposal, no provision for the submission of assurances was included whereby an investigator could avoid disqualification if the other criteria for disqualification were met. FDA received no comments on this approach.

Based on its more than 20 years of experience with the clinical investigator disqualification procedures, the agency believes that the disqualification procedure will operate more effectively and efficiently if it is limited to objective questions about whether there have been violations of FDA's regulations. The more subjective question of when assurances of future compliance are adequate should be addressed independently of the hearing proceeding. Under the procedures adopted in this final rule, assurances may be presented at several stages of a disqualification proceeding: (1) When the agency initiates a disqualification action, (2) at the informal conference with the Center for Drugs and Biologics offered before any hearing, (3) during the negotiations on a consent agreement, and (4) after an investigator

has been disqualified, as part of the efforts to obtain reinstatement. See § 312.70 of this rule and the guidelines for reinstating the eligibility of clinical investigators to receive investigational articles, announced in the *Federal Register* of November 19, 1982 (47 FR 52228). Deletion of the submission of "adequate assurances" as a ground for avoiding disqualification will affect only proceedings for which a notice of opportunity for hearing is issued after the effective date of this rule.

FDA acknowledges that proposed Part 54 contained additional criteria for clinical investigator disqualification that are not being adopted in this final rule. These criteria related to the significance of the regulatory violation; i.e., whether the violations adversely affected the validity of the study or the rights or safety of test subjects. The 1978 proposal also provided that the disqualification sanction would not be used if other lesser regulatory actions would be adequate.

FDA believes that these criteria are so subjective as to make them extremely difficult to apply fairly in disqualification proceedings. The agency emphasizes, however, that the agency retains discretion on whether to initiate an action to disqualify a clinical investigator, and that the Commissioner will exercise that discretion and not disqualify an investigator if the violations are insignificant, or if lesser sanctions would be adequate.

124. Several comments received on proposed Part 54 questioned FDA's authority under the act to disqualify clinical investigators. Because these comments are relevant to the disqualification procedures that are described both in the existing regulation and in this final rule, they are summarized and discussed below. One comment argued that none of the sections of the act that FDA cited in the preamble to proposed Part 54, that is, sections 701(a), 505(i), and 507(d), explicitly provides for or even suggests disqualification. Two comments suggested that the unsuccessful efforts of Congress to enact legislation to grant the agency explicit authority to disqualify investigators implies that FDA lacks authority now to disqualify clinical investigators.

FDA believes that the agency clearly has authority to disqualify clinical investigators that violate FDA's regulations. A thorough discussion of this authority is found in the preamble to proposed Part 52 (43 FR 35221). FDA believes it is unnecessary to restate that discussion here. In sum, although the concept of disqualification is not

explicitly mentioned in the act, the Supreme Court in *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973) has recognized that FDA has authority that "is implicit in the regulatory scheme, not spelled out in *haec verba*" in the statute. As stated in *Morrow v. Clayton*, 326 F.2d 36, 44 (10th Cir. 1963):

[I]t is a fundamental principle of administrative law that the powers of an administrative agency are not limited to those expressly granted by the [ir] statutes, but include, also, all of the powers that may be fairly implied therefrom.

See *Mourning v. Family Publications Service Inc.*, 411 U.S. 356 (1973) and *National Petroleum Refiners Association v. FTC*, 482, F.2d 672 (D.C. Cir. 1973). See also *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, cert denied, 423 U.S. 827 (1975); *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 246-248 (2d Cir. 1977); *American Frozen Food Institute v. Mathews* 413 F. Supp. 548 (D.D.C. 1976) aff'd per curiam, 555 F.2d 1059 (D.C. Cir. 1977); *National Confectioners Ass'n v. Califano*, 569 F.2d 690 (D.C. Cir. 1978); *National Ass'n of Pharmaceutical Manufacturers v. FDA*, 637 F.2d 877 (2d Cir. 1981).

Congressional inaction on proposed legislation that would state expressly an agency's authority to act does not support an inference that the agency lacks implicit authority to act under existing legislation. *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 381-382 n. 11 (1969). See also *Leist v. Simplot*, 638 F.2d 283, 318 (2d Cir. 1980), affirmed sub nom. *Merrill Lynch, Pierce, Fenner & Smith v. Curran*, 456 U.S. 353 (1982).

The agency concludes it has ample authority for the promulgation of procedures that govern the disqualification of an investigator of any FDA-regulated product who fails to carry out the requirements of these regulations.

125. The statement of clinical investigator responsibilities in this final rule is essentially the same as that contained in former § 312.1 with the exceptions noted above. However, in the former regulation, as noted below, clinical investigator responsibilities were described in forms (Forms FD-1572 and FD-1573) that were signed by the investigator and obtained by the sponsor. While FDA believes that the forms adequately stated the investigator's responsibilities, the

agency has concluded that a clearer approach is to set forth investigator responsibilities in the body of the text (see § 312.60 et seq.).

126. FDA recognizes that some may view the decision by the Ninth Circuit Court of Appeals in the *United States v. Smith*, 740 F.2d 734 (9th Cir. 1984), which involved criminal charges against a clinical investigator, as raising questions about the agency's authority to promulgate enforceable regulations on the obligations of clinical investigators. After considering the court's opinion, FDA concludes that it has ample authority to issue such regulations. The agency points out that the court in *Smith* noted that under the regulation then in effect (former 21 CFR 312.1(c)), FDA could conduct an administrative hearing to revoke an investigator's entitlement to work with investigational new drugs.

Moreover, FDA believes that both the language of the statute and its legislative history demonstrate that issuance of this final rule is within the scope of authority delegated to the Secretary by Congress under sections 505(i) and 701(a) of the act (21 U.S.C. 355(i) and 371(a)). The statutory language makes clear Congress' intent that clinical investigators be subject to section 505(i) of the act, and that they be required to maintain records. The stated purpose of section 505(i) is to make investigational drugs available "solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." The experts referred to are, in fact, the clinical investigators covered by this final rule, who perform the tests for which the investigational exemption exists. Section 505(i) of the act states that the "Secretary shall promulgate [exempting] regulations * * * [for] drugs intended solely for investigational use by experts * * *." Thus, it does not contain any restriction on who may be subject to such regulations.

The plain meaning of the statute demonstrates that Congress intended the Secretary to have the discretionary authority to impose conditions on investigational drug use in addition to those conditions specified as examples in the statute. The Secretary was explicitly authorized by Congress to impose "other conditions relating to the protection of the public health" by this part of the statute. 21 U.S.C. 355(i).

The legislative history of section 505(i) of the act also demonstrates that Congress intended the Secretary to require clinical investigators to maintain investigational drug study records. Before passage of the Drug Amendments of 1962 (Pub. L. 87-781), Congress was

aware that FDA had proposed regulations on new drugs for investigational use, including the requirement that investigators prepare and maintain records. See 27 FR 7990 (1962); 108 Congressional Record 17308 (1962) (remarks of Senator Eastland). The regulations were promulgated in 1963 (28 FR 179; January 8, 1963) and were codified in § 312.1. The House Committee Report specifically approved the proposed regulations and made clear what section 505(i) of the act was intended to accomplish.

[This section] provides a firm legal basis for greater controls of the distribution of new drugs for investigational use. Existing law directs the Secretary to promulgate regulations providing for exempting new drugs from preclearance for safety on condition that they are labeled and intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of new drugs. * * * These investigators are required to maintain records on the investigation. The Department has proposed strengthening regulations to provide greater safeguards in investigational drug use. The bill approves strengthening regulations and provides that the regulations may require, among other things, * * * (3) the establishment and maintenance of adequate records, * * * to facilitate the evaluation of the safety and effectiveness of the new drug, when an application is filed * * *. [This section also] amends the prohibited-acts section of existing law, section 301(e), 21 U.S.C. § 331(e), to forbid the failure to establish or maintain any required record, either on an investigational use of drugs or on clinical experience. * * *

H. Rept. 2464, 87th Cong., 2d Sess. 9-10 (1962) (emphasis added).

FDA views as unreasonable an interpretation of section 505(i) of the act that excludes regulation of clinical investigation from the public health protections provided by the section. A clinical investigator who falsified or destroyed original records of a drug study, and who then submitted false records to a sponsor, would clearly cause the sponsor to maintain false records and to make false reports to FDA. Moreover, were an investigator not required to maintain his or her own records (as distinct from those maintained by the sponsor), FDA would in those cases frequently be precluded from even discovering the falseness of the reports and would then review and perhaps approve drug products on the basis of false data.

Thus, section 505(i) provides ample authority for FDA to adopt these regulations, which have the force and effect of law.

Investigator Statement (§ 312.53(c))

127. Proposed and final § 312.53(c)(1) transforms the investigator statement

(Form FDA-1572) from a detailed description of the responsibilities of all parties to the investigation into a brief form that identifies the regulations governing conduct of a clinical investigation and commits the investigator to comply with these requirements. One comment expressed regret at this change, claiming that, as proposed, the clinical investigator would no longer have available a concise written statement of his or her obligations. The comment suggested that the regulations explicitly require the sponsor to provide the investigator with a written summary of all applicable responsibilities before the investigation begins.

FDA agrees with the comments on the usefulness of providing investigators with a written summary of their responsibilities in conducting a clinical investigation. The agency has therefore prepared an informational leaflet that summarizes investigator responsibilities imposed under this part and other relevant requirements of FDA's regulations. This leaflet can be obtained from the Legislative, Professional, and Consumer Affairs Branch (HFN-365), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 (301-295-8012).

Because FDA is making available a written summary of investigator responsibilities, the agency does not believe that this final rule should require sponsor distribution of similar materials to investigators.

128. Section 312.53(c) requires that the investigator statement identify the name and address of the IRB that is responsible for review and approval of the investigator's study. One comment suggested that it would be inappropriate and impracticable to include this information in the investigator statement.

FDA disagrees with this comment. An investigator is responsible for obtaining IRB approval of a clinical investigation before a study may be initiated, and for keeping the sponsor informed of such IRB approval and subsequent IRB actions concerning the study. FDA does not believe it is a significant additional burden to ask the investigator to inform the sponsor of the IRB's name and address. The cooperation of investigators in this matter will help the sponsor to meet its responsibility to keep the agency informed of the identity of all reviewing IRB's.

129. One comment asked that the proposed commitment of the investigator to "report to the sponsor immediately any unsuspected or serious

side effects that occur in the course of the investigation(s)" (proposed § 312.53(c)(1)(vi)(e)) be revised to require the reporting of any "unexpected or serious side effects."

FDA has revised § 312.53(c)(1)(vi)(e) to require the investigator to report adverse experiences in accordance with the provisions of § 312.64. Section 312.64 requires an investigator promptly to report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the regulation requires the investigator to report immediately. These provisions are taken almost verbatim from former § 312.1.

130. A comment objected to the provision in § 312.53(c)(3) that would require the sponsor to obtain a clinical plan from each participating investigator. The comment stated its assumption that the sponsor is ordinarily responsible for developing the plan, and that the sponsor normally provides the plan to participating investigators rather than the other way around. Another comment contended that the use of the term "clinical plan" is confusing, as it usually refers to the overall plan of the sponsor. The comment suggested using "protocol" or "clinical protocol" instead.

FDA agrees that the use of the term "protocol" alone may be less confusing and has revised § 312.53(c)(3) of the final rule accordingly.

The final rule is not intended to designate whether the investigator or the sponsor originate the protocol under which a study will be conducted. The inclusion of the protocol in the information given by the investigator to the sponsor simply provides added assurance that there has been a "meeting of the minds" between sponsor and investigator on the appropriate course for the study.

Informing Investigators (§ 312.55)

131. One comment contended that the intended relationship between the investigator notification requirements of § 312.32 dealing with notifying investigators of IND safety reports and those outlined in § 312.55(b) dealing with important safety information is unclear. The comment contended that § 312.55 should not require more with respect to notification than is required under the IND safety report requirement. The comment observed that proposed § 312.55(b) can be read to require that safety information other than that contained in the safety reports be conveyed to investigators on an immediate basis. If that is what was intended, the comment asked the agency

to specify what other information should be conveyed to investigators and what need there is for conveying that additional information.

FDA did not intend that § 312.55(b) differ from § 312.32 with respect to investigator notification of important safety information. FDA has revised § 312.55(b) to clarify that important safety information shall be relayed in safety reports to the investigator in accordance with § 312.32.

Review of Ongoing Investigations (§ 312.56)

132. Proposed § 212.56 directed sponsors to "evaluate the evidence relating to safety and effectiveness of the drug as it is obtained from the investigators." One comment claimed that, since it is not ordinarily possible to evaluate evidence of effectiveness without breaking the code for blinded studies, the preamble to the final regulation should make clear that, for blinded studies, evidence is not considered "obtained" until the code is broken.

The agency views § 312.56(c) as requiring a sponsor to: (1) Immediately review all new data received from an investigator regarding the safety of the investigational drug, (2) periodically evaluate all data received from all investigators regarding the safety of the drug, and (3) periodically evaluate the data received from all investigators who have completed their portions of the investigation to ascertain whether the drug is proving to be effective for the intended use. As thus interpreted, a sponsor should not have to "break the code" of a blinded study to evaluate evidence relating solely to the effectiveness of the investigational drug.

133. If an investigation is discontinued for safety reasons, § 312.56(d) (§ 312.56(c) as proposed) requires the sponsor to notify all reviewing IRB's of the discontinuance. One comment asked whether the sponsor's obligation would be limited to notifying only those IRB's reviewing studies involving the specific dosage level and dosage form of the problem drug, or whether the obligation would extend to notifying all IRB's reviewing studies of the drug at any dosage level or in any dosage form. Two other comments suggested that the responsibility for notifying an IRB should belong with the investigator, not the sponsor.

The notification requirement in § 312.56(d) applies to all IRB's reviewing clinical investigations with the investigational drug. The notification provides added assurance that reviewing IRB's will be promptly

informed of the most serious problems relating to their review.

With respect to the comments suggesting that the investigator, not the sponsor, has the responsibility for IRB notification, FDA recognizes that sponsors usually do not have direct contact with IRB's. FDA believes, however, that under extraordinary circumstances, such as when a sponsor discontinues a study because an adverse drug effect presents an unreasonable and significant risk to subjects, it is not unreasonable to ask the sponsor to notify all reviewing IRB's of the discontinuance. Direct contact between the sponsor and IRB in this situation will permit an IRB to obtain directly from the sponsor all the facts surrounding the sponsor's decision to discontinue the study, information that may not be available from the investigator.

134. Under § 312.56(d) (§ 312.56(c) as proposed), if a sponsor determines that its investigational drug presents an unreasonable and significant risk to subjects, the sponsor is required to discontinue the investigation as soon as possible, and in no event later than 5 working days after making the determination. One comment agreed that the 5-working-day time limit should apply to the entry of new subjects to the investigation, but argued that the provision should be revised to permit the investigator to take participating subjects off the drug "in a fashion consistent with the health and safety of the subjects."

Once a determination has been made that an investigational drug presents an unreasonable and significant risk to subjects—the trigger for discontinuance—the agency believes it is reasonable to expect sponsors to ensure that subjects are taken off the drug as quickly as possible. FDA believes that, as a general rule, 5 working days is sufficient time for patients to be taken off the drug in a fashion consistent with their health and safety. If, in the sponsor's view, there are extraordinary circumstances dictating that some subjects be continued on the drug, FDA will be willing on a case-by-case basis to discuss an extension of the 5-day time limit.

Inspection of Sponsor's Records and Reports (§ 312.58)

135. Proposed § 312.58(a) would require the sponsor to make available for FDA inspection and copying the records and reports that are required to be maintained by the sponsor under Part 312 and other applicable regulations.

One comment argued that reports made by a sponsor's monitor should not be subject to this provision because monitoring, as a quality assurance function, will work most efficiently if it is not subject to government audit. In this way, the comment contended, monitors' reports will be more candid and critical, and thus have more value to the sponsor in assuring that appropriate corrective actions are undertaken as needed.

FDA believes it should retain the authority to inspect records and reports relating to a sponsor's monitoring of clinical investigations under Part 312. Access to these materials helps the agency both to confirm that monitoring is actually taking place and to determine the nature of such monitoring. FDA also is not persuaded that the prospect of agency inspection of monitoring records and reports should significantly influence monitors in recording their observations and recommendations.

As proposed, § 312.58(a) would have required sponsors to make available to FDA's inspectors "reports required to be maintained under this part and under other applicable parts of this chapter." This might be read as not requiring a sponsor to make available a record or report that is not specifically enumerated in the regulations, even though it is clearly related to the conduct of a clinical investigation. To clarify agency intent, FDA has revised § 312.58(a) in the final rule to give the agency explicit authority to inspect and copy any record or report relating to a clinical investigation conducted under Part 312.

Imports (§ 312.110(a))

136. The proposal provided that an investigational drug may be imported if it complies with Part 312 and the consignee of the shipment is either the sponsor of the study or is an investigator named in the IND. One comment noted that a domestic agent may act as intermediary for a foreign sponsor, receiving the drug directly from the foreign sponsor, and monitoring and controlling its distribution. The comment suggested that shipment directly to this class of consignees be made expressly allowable.

The agency has no objection to the importation of a drug into the United States going through an agent of a foreign sponsor provided: (a) The intermediary is identified in the IND and (b) the IND describes what, if any, actions the intermediary will take with respect to the imported drug (e.g., repacking or relabeling). FDA has revised the regulation accordingly.

137. One comment asked that FDA give sponsors guidance on the procedures to be followed in importing a new drug for use in laboratory research or for tests *in vitro*.

The import into the United States of a drug intended for investigational use in laboratory research animals or tests *in vitro* must comply with the requirements set forth in proposed and final § 312.160 governing authorization to ship such drug. This section requires the shipper to ensure that the drug is properly labeled, that due diligence is taken to ensure that the drug is shipped only to experts regularly engaged in conducting tests in animals or *in vitro*, and that accurate records are kept of the drug's distribution. It should be noted that § 312.160 only governs compliance with the Federal Food, Drug, and Cosmetic Act; a sponsor may face import requirements under other laws and administered by other agencies, such as laws governing importation of controlled substances.

138. One comment suggested that the import provisions of proposed § 312.110(a) should be revised to allow a sponsor to import an investigational new drug for use as a control in a comparative study involving the sponsor's own drug without requiring a separate IND for the comparison drug. The comment suggested that the importation of the drug could be accommodated by allowing the sponsor to insert all necessary relevant information in the sponsor's existing IND file, thus obviating the need to create a separate IND for the imported drug.

As an administrative convenience and to ensure that information on both the investigational drug and the drug used as an active control are reviewed together, the two drugs should be included in the same IND. The sponsor should, of course, ensure that sufficient information is submitted on the control drug to permit an assessment of the drug's safety for use in the investigation, and to permit the drug to be used as a baseline of effectiveness against which to measure the effectiveness of the principal drug under study. (Sponsors are reminded that when an active treatment control is used, FDA expects such control to be a known effective therapy. See 21 CFR 314.126(b)(2)(iv).)

Exports (§ 312.110(b))

139. Proposed § 312.110(b)(1) would permit export of an investigational new drug if an IND is in effect for the drug and each person who receives the drug is an investigator named in the application. Several comments contended that, as written, this

provision could be interpreted as prohibiting the intra-company export of investigational drugs, a practice which the comment suggested was common under the current regulations. The practice allows a shipment from the United States company to go first to its parent, subsidiary, or affiliate company in a foreign country for final distribution by the foreign affiliate to the clinical investigator. One comment stated that shipping through a foreign affiliate permits the sponsor to save multiple shipping expenses and to ensure proper storage conditions upon receipt. The comment stated its assumption that FDA did not intend to prohibit this practice and urged that the final regulation so state.

The agency has no objection to either a domestic or an export shipment of an investigational drug subject to an IND going through an intermediary on its way to the clinical investigator provided the IND identifies the intermediary and describes what actions, if any, the intermediary will take with respect to the drug. Of course, the IND would still be required to identify and give the qualifications for each participating investigator.

140. One comment questioned the applicability of the IND export provisions to the export of antibiotic drugs. The comment noted that, on its face, the export provisions apply to any investigational new drug including antibiotic drugs. The comment claimed that these provisions could be interpreted to mean that an unapproved antibiotic drug could not be exported except in accordance with the investigational export provisions. The comment claimed that this would be inconsistent with FDA's previously expressed view that the act does not require an IND for the export of an unapproved antibiotic drug intended for use in humans if the standards of section 801(d) of the act (21 U.S.C. 381(d)) are met. The comment asked for clarification of the agency's view in the final regulation.

The comment is correct in noting that antibiotic drug products, including investigational antibiotic drug products, may be exported under the provisions of section 801(d) of the act. FDA has added new § 312.110(b)(4) to state that, notwithstanding the export provisions of the IND regulations, an investigational antibiotic may be exported if its export conforms to the provisions of section 801(d) of the act.

141. It should be noted that, under the recently adopted Drug Exports Amendments Act of 1986, FDA is authorized to approve applications to

export unapproved drugs (including biological products). New section 802 of the Federal Food, Drug, and Cosmetic Act and section 351(h)(1)(A) of the Public Health Service Act describe the conditions that a drug firm must satisfy to obtain FDA approval to export unapproved products for commercial marketing abroad. FDA has revised § 312.110(b) to make clear that the IND export provisions do not preclude the export of products that are approved for export under the new law.

142. In the *Federal Register* of January 18, 1984 (49 FR 2095), FDA amended the IND regulations to streamline the process by which the agency may authorize the export of investigational new drugs that are not subject to an effective IND. Specifically, these revisions allow the agency to authorize export in two situations: (a) In response to a request submitted by a drug firm containing sufficient information to demonstrate that the drug is appropriate for investigational use, that the drug will be used for investigational purposes only, and that the drug can legally be used by the consignee in the importing country for the proposed investigational use; and (b) in response to a request submitted by an authorized official of the government of the importing country, submitted directly to FDA, that specifies that the government has adequate information about the drug for the proposed use, that the drug will be used for investigational purposes only, and that the drug can legally be used in the importing country. These two provisions have been incorporated into this final rule (§ 312.110(b)(2)).

Foreign Clinical Studies Not Conducted Under an IND (§ 312.120)

143. One comment noted that a foreign clinical investigation conducted under an IND is required to conform to FDA's current IRB regulations, whereas a foreign study not conducted under an IND is deemed acceptable if it complies with the ethical principles of the Declaration of Helsinki. The comment questioned the disparate treatment of these studies and suggested that the final rule should eliminate the distinction between them so that compliance with the ethical principles of the Declaration of Helsinki would meet the ethical requirements for any foreign study, whether conducted under an IND or not.

The distinction referred to in the comment is not a product of the new regulations, but rather carries forward the past requirement under former § 312.20. FDA believes this distinction is warranted for the following reasons.

First, the agency believes that any study under an IND, wherever it is conducted, should comply with all applicable requirements governing the conduct of clinical studies, including the requirement for institutional review. To exempt foreign studies under an IND from IRB requirements might encourage sponsors to remove clinical studies from the United States to countries with lesser standards of human subject protection. This would clearly not be in the interest of the public health.

While FDA is unwilling to create a different standard for foreign studies under an IND, the agency will accept in support of an IND or marketing application reports of foreign studies that are not under an IND (and not subject to institutional review), provided there are adequate alternative guarantees of human subject protection. This policy is based on a recognition that much important clinical research is conducted throughout the world, which meets the legal and ethical standards of the countries in which it is conducted, but which is carried on without the kind of institutional review required under FDA's requirements. To insist on absolute adherence to FDA's IRB requirements would obligate the agency to reject valid scientific data generated overseas. Thus, § 312.120 (like its predecessor § 312.20) permits FDA to accept a foreign study not subject to institutional review, provided the study was conducted in accordance with the Declaration of Helsinki or the laws of the foreign country in which the research was conducted, whichever affords the greater protection of the individual.

Finally, FDA notes that § 56.105 of the IRB regulations permits a waiver of IRB review where that is warranted. Thus, foreign research can be conducted under an IND even where IRB review is not available, provided a waiver from the agency is obtained in advance.

On its own initiative, FDA has revised § 312.120(b) to make clear that the data submission requirements for foreign studies in paragraph (b) apply not only to foreign studies intended to support an IND, but also to such studies when submitted in support of a marketing application. The revision conforms the final rule to previous agency policy.

144. Proposed and final § 312.120(b)(3) requires that case records from a foreign study be submitted if FDA so requests. One comment suggested that the laws and regulations of some foreign countries may not permit the submission of case records and urged that the final regulation provide for other means of

assuring the validity of information in a foreign study.

FDA understands that a sponsor cannot disclose foreign records that are prohibited from disclosure by foreign law. Nevertheless, if the agency believes that access to records is necessary to verify certain data or to validate the study—and such records are not available because of foreign law—the sponsor and FDA will need to agree upon an alternative validating procedure if the agency is to rely on the data. Such alternative validation might entail the verification of data by a foreign drug regulatory body or other mutually agreed on procedure.

145. One comment supported FDA's proposals to accept foreign clinical studies in support of IND applications and applications for marketing permits, but urged that the assumption should be that these studies are acceptable unless FDA can demonstrate why the studies are not acceptable.

FDA disagrees with this comment's suggestion that the burden of proof should be on FDA to show why a foreign study is inadequate. As with domestic studies, the burden is on the sponsor to demonstrate that a study is valid. Nevertheless, FDA routinely gives sponsors its reasons for refusing to accept a study, whether foreign or domestic, and that practice will continue.

146. Section 312.120 requires a sponsor who wishes to rely on a foreign clinical study to submit a description of the research facilities used during the study. One comment recommended deleting the requirement, observing that such description is not required for studies under an IND.

FDA disagrees. An assessment of the adequacy of research facilities for a proposed investigation is an important factor in determining the reliability and validity of data generated by a study, wherever the study is conducted. For studies conducted under an IND, this assessment is frequently obtained through on-site inspections of the facilities identified in the IND. However, because of the difficulties in inspecting foreign research facilities and because of the likelihood that FDA will not otherwise be familiar with such facilities, FDA believes it is appropriate to require documentation of the adequacy of foreign facilities. The requirement should not represent a significant burden on sponsors, but will appreciably enhance FDA's review of the quality of foreign studies.

147. One comment recommended that FDA not require a sponsor wishing to rely on a foreign study to submit the

names and qualifications of members of that study's reviewing IRB or other independent review committee when such information is not required of a domestic study.

Information about the qualifications of such review committee members is important in assessing the competence of the committee to protect the interests of human subjects. While it is true that the sponsor of a study under an IND is not required to submit the names and qualifications of the members of an independent review committee, the information is routinely obtained through FDA on-site inspections of the IRB. To obtain comparable insight into the quality of institutional review for foreign studies not conducted under an IND, given that inspections of foreign review committees are usually not feasible, FDA believes it is appropriate to ask that the sponsor document the qualifications of the institutional committee members. FDA notes that this provision is not a new requirement, but has been part of FDA's regulations since 1975.

Availability for Public Disclosure of Data and Information in an IND (§ 312.130)

148. Proposed § 312.130 provided that the existence of an IND will not be disclosed or acknowledged. One comment urged that this section be revised to state that, unless such public disclosure is clear and a matter of public record, existence of an IND will not be disclosed by FDA without consulting with a sponsor. The comment argued that unless FDA has a clear record of a previous disclosure, the sponsor is most likely to know whether the existence of the IND has been publicly divulged.

FDA's longstanding policy has been not to disclose the existence of an IND unless its existence has previously been disclosed. Where there is any doubt about previous disclosure, the burden is placed on the requestor to demonstrate such disclosure. As this procedure for screening requests has worked well, FDA does not believe the suggested change is needed.

Drugs for Investigational Use in Laboratory Research Laboratories or In Vitro Tests (§ 312.160)

149. The proposal provided that if authority to ship a drug for use in laboratory research animals or in vitro is terminated, the person shipping the drug must recall or have destroyed the unused supplies of the drug. One comment contended that there should be no need to destroy supplies that may possibly be in short supply and suggested that the provision be revised

to permit disposal of the drug in some other way.

FDA agrees with the comment and has revised the final rule by adding new paragraph (c) to § 312.160 to permit a shipper of a drug for investigational use in vitro or in research animals to authorize alternative disposition of unused supplies of the investigational drug, once the investigation is ended. The right to provide an alternative disposition is conditioned on the shipper assuring that the unused supplies will not expose humans to risks from the drug, either directly or indirectly.

List of Subjects

21 CFR Part 312

Drugs, Medical research.

21 CFR Part 314

Administrative practice and procedure, Drugs.

21 CFR Part 511

Animal drugs, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 514

Administrative practice and procedure, Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, 21 CFR Chapter I is amended as follows:

1. By reviewing Part 312 to read as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

Subpart A—General Provisions

Sec.

- 312.1 Scope.
- 312.2 Applicability.
- 312.3 Definitions and interpretations.
- 312.6 Labeling of an investigational new drug.
- 312.7 Promotion and sale of investigational drugs.
- 312.10 Waivers.

Subpart B—Investigational New Drug Application (IND)

Sec.

- 312.20 Requirement for an IND.
- 312.21 Phases of an investigation.
- 312.22 General principles of the IND submission.
- 312.23 IND content and format.
- 312.30 Protocol amendments.
- 312.31 Information amendments.
- 312.32 IND safety reports.
- 312.33 Annual reports.
- 312.34 Treatment use of an investigational new drug. [Reserved]
- 312.36 Emergency use of an investigational new drug.
- 312.38 Withdrawal of an IND.

Subpart C—Administrative Actions

Sec.

- 312.40 General requirements for use of an investigational new drug in a clinical investigation.
- 312.41 Comment and advice on an IND.
- 312.42 Clinical holds and requests for modification.
- 312.44 Termination.
- 312.45 Inactive status.
- 312.47 Meetings.
- 312.48 Dispute resolution.

Subpart D—Responsibilities of Sponsors and Investigators

- 312.50 General responsibilities of sponsors.
- 312.52 Transfer of obligations to a contract research organization.
- 312.53 Selecting investigators and monitors.
- 312.55 Informing investigators.
- 312.56 Review of ongoing investigations.
- 312.57 Recordkeeping and record retention.
- 312.58 Inspection of sponsor's records and reports.
- 312.59 Disposition of unused supply of investigational drug.
- 312.60 General responsibilities of investigators.
- 312.61 Control of the investigational drug.
- 312.62 Investigator recordkeeping and record retention.
- 312.64 Investigator reports.
- 312.66 Assurance of IRB review.
- 312.68 Inspection of investigator's records.
- 312.69 Handling of controlled substances.
- 312.70 Disqualification of a clinical investigator.

Subpart E—Miscellaneous

- 312.110 Import and export requirements.
- 312.120 Foreign clinical studies not conducted under an IND.
- 312.130 Availability for public disclosure of data and information in an IND.
- 312.140 Address for correspondence.
- 312.145 Guidelines.

Subpart F—Drugs for Investigational Use in Laboratory Research Animals or in Vitro Tests

312.160 Drugs for investigational use in laboratory research animals or in vitro tests.

Authority: Secs. 501, 502, 503, 505, 506, 507, 701, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 351, 352, 353, 355, 356, 357, 371); sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262); 21 CFR 5.10, 5.11.

Subpart A—General Provisions

§ 312.1 Scope.

- (a) This part contains procedures and requirements governing the use of investigational new drugs, including procedures and requirements for the submission to, and review by, the Food and Drug Administration of investigational new drug applications (IND's). An investigational new drug for which an IND is in effect in accordance with this part is exempt from the

premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug.

(b) References in this part to regulations in the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 312.2 Applicability.

(a) *Applicability.* Except as provided in this section, this part applies to all clinical investigations of products that are subject to section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or to the licensing provisions of the Public Health Service Act (58 Stat. 632, as amended (42 U.S.C. 201 et seq.)).

(b) *Exemptions.* (1) The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if all the following apply:

(i) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;

(ii) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;

(iii) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

(iv) The investigation is conducted in compliance with the requirements for institutional review set forth in Part 56 and with the requirements for informed consent set forth in Part 50; and

(v) The investigation is conducted in compliance with the requirements of § 312.7.

(2)(i) A clinical investigation involving an in vitro diagnostic biological product listed in paragraph (b)(2)(ii) of this section is exempt from the requirements of this part if (a) it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and (b) it is shipped in compliance with § 312.160.

(ii) In accordance with paragraph (b)(2)(ii) of this section, the following products are exempt from the requirements of this part: (a) blood grouping serum; (b) reagent red blood cells; and (c) anti-human globulin.

(3) A drug intended solely for tests in vitro or in laboratory research animals

is exempt from the requirements of this part if shipped in accordance with § 312.160.

(4) FDA will not accept an application for an investigation that is exempt under the provisions of paragraph (b)(1) of this section.

(5) A clinical investigation involving use of a placebo is exempt from the requirements of this part if the investigation does not otherwise require submission of an IND.

(c) *Bioavailability studies.* The applicability of this part to in vivo bioavailability studies in humans is subject to the provisions of § 320.31.

(d) *Unlabeled indication.* This part does not apply to the use in the practice of medicine for an unlabeled indication of a new drug or antibiotic drug product approved under Part 314 or of a licensed biological product.

(e) *Guidance.* FDA may, on its own initiative, issue guidance on the applicability of this part to particular investigational uses of drugs. On request, FDA will advise on the applicability of this part to a planned clinical investigation.

§ 312.3 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the act apply to those terms when used in this part:

(b) The following definitions of terms also apply to this part:

"Act" means the Federal Food, Drug, and Cosmetic Act (secs. 201-902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 301-392)).

"Clinical investigation" means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

"Contract research organization" means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.

"FDA" means the Food and Drug Administration.

"IND" means an investigational new drug application. For purposes of this part, "IND" is synonymous with "Notice of Claimed Investigational Exemption for a New Drug."

"Investigational new drug" means a new drug, antibiotic drug, or biological drug that is used in a clinical investigation. The term also includes a

biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part.

"Investigator" means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team.

"Marketing application" means an application for a new drug submitted under section 505(b) of the act, a request to provide for certification of an antibiotic submitted under section 507 of the act, or a product license application for a biological product submitted under the Public Health Service Act.

"Sponsor" means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

"Sponsor-Investigator" means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.

"Subject" means a human who participates in an investigation, either as a recipient of the investigational new drug or as a control. A subject may be a healthy human or a patient with a disease.

§ 312.6 Labeling of an investigational new drug.

(a) The immediate package of an investigational new drug intended for human use shall bear a label with the statement "Caution: New Drug—Limited by Federal (or United States) law to investigational use."

(b) The label or labeling of an investigational new drug shall not bear

any statement that is false or misleading in any particular and shall not represent that the investigational new drug is safe or effective for the purposes for which it is being investigated.

§ 312.7 Promotion and sale of investigational drugs.

(a) *Promotion of an investigational new drug.* A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

(b) *Commercial distribution of an investigational new drug.* A sponsor or investigator shall not commercially distribute or test market an investigational new drug.

(c) *Prolonging an investigation.* A sponsor shall not unduly prolong an investigation after finding that the results of the investigation appear to establish sufficient data to support a marketing application.

(d) *Sale of an investigational drug.* If the drug is to be sold, the sponsor should submit a notification to FDA providing a full explanation why sale is required and why the sale should not be regarded as the commercialization of a new drug for which an application is not approved.

§ 312.10 Waivers.

(a) A sponsor may request FDA to waive applicable requirement under this part. A waiver request may be submitted either in an IND or in an information amendment to an IND. In an emergency, a request may be made by telephone or other rapid communication means. A waiver request is required to contain at least one of the following:

(1) An explanation why the sponsor's compliance with the requirement is unnecessary or cannot be achieved;

(2) A description of an alternative submission or course of action that satisfies the purpose of the requirement; or

(3) Other information justifying a waiver.

(b) FDA may grant a waiver if it finds that the sponsor's noncompliance would

not pose a significant and unreasonable risk to human subjects of the investigation and that one of the following is met:

(1) The sponsor's compliance with the requirement is unnecessary for the agency to evaluate the application, or compliance cannot be achieved;

(2) The sponsor's proposed alternative satisfies the requirement; or

(3) The applicant's submission otherwise justifies a waiver.

Subpart B—Investigational New Drug Application (IND)

§ 312.20 Requirement for an IND.

(a) A sponsor shall submit an IND to FDA if the sponsor intends to conduct a clinical investigation with an investigational new drug that is subject to § 312.2(a).

(b) A sponsor shall not begin a clinical investigation subject to § 312.2(a) until the investigation is subject to an IND which is in effect in accordance with § 312.40.

§ 312.21 Phases of an investigation.

An IND may be submitted for one or more phases of an investigation. The clinical investigation of a previously untested drug is generally divided into three phases. Although in general the phases are conducted sequentially, they may overlap. These three phases of an investigation are as follows:

(a) *Phase 1.* (1) Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. The total number of subjects and patients included in Phase 1 studies varies with the drug, but is generally in the range of 20 to 80.

(2) Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

(b) *Phase 2.* Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the

common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

(c) *Phase 3.* Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects.

§ 312.22 General principles of the IND submission.

(a) FDA's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phase 2 and 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety. Therefore, although FDA's review of Phase 1 submissions will focus on assessing the safety of Phase 1 investigations, FDA's review of Phases 2 and 3 submissions will also include an assessment of the scientific quality of the clinical investigations and the likelihood that the investigations will yield data capable of meeting statutory standards for marketing approval.

(b) The amount of information on a particular drug that must be submitted in an IND to assure the accomplishment of the objectives described in paragraph (a) of this section depends upon such factors as the novelty of the drug, the extent to which it has been studied previously, the known or suspected risks, and the developmental phase of the drug.

(c) The central focus of the initial IND submission should be on the general investigational plan and the protocols for specific human studies. Subsequent amendments to the IND that contain new or revised protocols should build logically on previous submissions and should be supported by additional information, including the results of animal toxicology studies or other human studies as appropriate. Annual reports to the IND should serve as the focus for reporting the status of studies being conducted under the IND and should update the general investigational plan for the coming year.

(d) The IND format set forth in § 312.23 should be followed routinely by sponsors in the interest of fostering an efficient review of applications. Sponsors are expected to exercise considerable discretion, however, regarding the content of information submitted in each section, depending upon the kind of drug being studied and the nature of the available information. Section 312.23 outlines the information needed for a commercially sponsored IND for a new molecular entity. A sponsor-investigator who uses, as a research tool, an investigational new drug that is already subject to a manufacturer's IND or marketing application should follow the same general format, but ordinarily may, if authorized by the manufacturer, refer to the manufacturer's IND or marketing application in providing the technical information supporting the proposed clinical investigation. A sponsor-investigator who uses an investigational drug not subject to a manufacturer's IND or marketing application is ordinarily required to submit all technical information supporting the IND, unless such information may be referenced from the scientific literature.

§ 312.23 IND content and format.

(a) A sponsor who intends to conduct a clinical investigation subject to this part shall submit an "Investigational New Drug Application" (IND) including, in the following order:

(1) *Cover sheet (Form FDA-1571).* A cover sheet for the application containing the following:

(i) The name, address, and telephone number of the sponsor, the date of the application, and the name of the investigational new drug.

(ii) Identification of the phase or phases of the clinical investigation to be conducted.

(iii) A commitment not to begin clinical investigations until an IND covering the investigations is in effect.

(iv) A commitment that an Institutional Review Board (IRB) that complies with the requirements set forth in Part 56 will be responsible for the initial and continuing review and approval of each of the studies in the proposed clinical investigation and that the investigator will report to the IRB proposed changes in the research activity in accordance with the requirements of Part 56.

(v) A commitment to conduct the investigation in accordance with all other applicable regulatory requirements.

(vi) The name and title of the person responsible for monitoring the conduct

and progress of the clinical investigations.

(vii) The name(s) and title(s) of the person(s) responsible under § 312.32 for review and evaluation of information relevant to the safety of the drug.

(viii) If a sponsor has transferred any obligations for the conduct of any clinical study to a contract research organization, a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred. If all obligations governing the conduct of the study have been transferred, a general statement of this transfer—in lieu of a listing of the specific obligations transferred—may be submitted.

(ix) The signature of the sponsor or the sponsor's authorized representative. If the person signing the application does not reside or have a place of business within the United States, the IND is required to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.

(2) *A table of contents.*

(3) *Introductory statement and general investigational plan.* (i) A brief introductory statement giving the name of the drug and all active ingredients, the drug's pharmacological class, the structural formula of the drug (if known), the formulation of the dosage form(s) to be used, the route of administration, and the broad objectives and planned duration of the proposed clinical investigation(s).

(ii) A brief summary of previous human experience with the drug, with reference to other IND's if pertinent, and to investigational or marketing experience in other countries that may be relevant to the safety of the proposed clinical investigation(s).

(iii) If the drug has been withdrawn from investigation or marketing in any country for any reason related to safety or effectiveness, identification of the country(ies) where the drug was withdrawn and the reasons for the withdrawal.

(iv) A brief description of the overall plan for investigating the drug product for the following year. The plan should include the following: (a) The rationale for the drug or the research study; (b) the indication(s) to be studied; (c) the general approach to be followed in evaluating the drug; (d) the kinds of clinical trials to be conducted in the first year following the submission (if plans are not developed for the entire year, the sponsor should so indicate); (e) the estimated number of patients to be given the drug in those studies; and (f) any

risks of particular severity or seriousness anticipated on the basis of the toxicological data in animals or prior studies in humans with the drug or related drugs.

(4) [Reserved]

(5) *Investigator's brochure.* If required under § 312.55, a copy of the investigator's brochure, containing the following information:

(i) A brief description of the drug substance and the formulation, including the structural formula, if known.

(ii) A summary of the pharmacological and toxicological effects of the drug in animals and, to the extent known, in humans.

(iii) A summary of the pharmacokinetics and biological disposition of the drug in animals and, if known, in humans.

(iv) A summary of information relating to safety and effectiveness in humans obtained from prior clinical studies. (Reprints of published articles on such studies may be appended when useful.)

(v) A description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or with related drugs, and of precautions or special monitoring to be done as part of the investigational use of the drug.

(6) *Protocols.* (i) A protocol for each planned study. (Protocols for studies not submitted initially in the IND should be submitted in accordance with

§ 312.30(a).) In general, protocols for Phase 1 studies may be less detailed and more flexible than protocols for Phase 2 and 3 studies. Phase 1 protocols should be directed primarily at providing an outline of the investigation—an estimate of the number of patients to be involved, a description of safety exclusions, and a description of the dosing plan including duration, dose, or method to be used in determining dose—and should specify in detail only those elements of the study that are critical to safety, such as necessary monitoring of vital signs and blood chemistries. Modifications of the experimental design of Phase 1 studies that do not affect critical safety assessments are required to be reported to FDA only in the annual report.

(ii) In Phases 2 and 3, detailed protocols describing all aspects of the study should be submitted. A protocol for a Phase 2 or 3 investigation should be designed in such a way that, if the sponsor anticipates that some deviation from the study design may become necessary as the investigation progresses, alternatives or contingencies to provide for such deviation are built into the protocols at the outset. For example, a protocol for a controlled

short-term study might include a plan for an early crossover of nonresponders to an alternative therapy.

(iii) A protocol is required to contain the following, with the specific elements and detail of the protocol reflecting the above distinctions depending on the phase of study:

(a) A statement of the objectives and purpose of the study.

(b) The name and address and a statement of the qualifications (curriculum vitae or other statement of qualifications) of each investigator, and the name of each subinvestigator (e.g., research fellow, resident) working under the supervision of the investigator; the name and address of the research facilities to be used; and the name and address of each reviewing Institutional Review Board.

(c) The criteria for patient selection and for exclusion of patients and an estimate of the number of patients to be studied.

(d) A description of the design of the study, including the kind of control group to be used, if any, and a description of methods to be used to minimize bias on the part of subjects, investigators, and analysts.

(e) The method for determining the dose(s) to be administered, the planned maximum dosage, and the duration of individual patient exposure to the drug.

(f) A description of the observations and measurements to be made to fulfill the objectives of the study.

(g) A description of clinical procedures, laboratory tests, or other measures to be taken to monitor the effects of the drug in human subjects and to minimize risk.

(7) *Chemistry, manufacturing, and control information.* (i) As appropriate for the particular investigations covered by the IND, a section describing the composition, manufacture, and control of the drug substance and the drug product. Although in each phase of the investigation sufficient information is required to be submitted to assure the proper identification, quality, purity, and strength of the investigational drug, the amount of information needed to make that assurance will vary with the phase of the investigation, the proposed duration of the investigation, the dosage form, and the amount of information otherwise available. FDA recognizes that modifications to the method of preparation of the new drug substance and dosage form and changes in the dosage form itself are likely as the investigation progresses. Therefore, the emphasis in an initial Phase 1 submission should generally be placed on the identification and control of the raw materials and the new drug

substance. Final specifications for the drug substance and drug product are not expected until the end of the investigational process.

(ii) It should be emphasized that the amount of information to be submitted depends upon the scope of the proposed clinical investigation. For example, although stability data are required in all phases of the IND to demonstrate that the new drug substance and drug product are within acceptable chemical and physical limits for the planned duration of the proposed clinical investigation, if very short-term tests are proposed, the supporting stability data can be correspondingly limited.

(iii) As drug development proceeds and as the scale or production is changed from the pilot-scale production appropriate for the limited initial clinical investigations to the larger-scale production needed for expanded clinical trials, the sponsor should submit information amendments to supplement the initial information submitted on the chemistry, manufacturing, and control processes with information appropriate to the expanded scope of the investigation.

(iv) Reflecting the distinctions described in this paragraph (a)(7), and based on the phase(s) to be studied, the submission is required to contain the following:

(a) *Drug substance.* A description of the drug substance, including its physical, chemical, or biological characteristics; the name and address of its manufacturer; the general method of preparation of the drug substance; the acceptable limits and analytical methods used to assure the identity, strength, quality, and purity of the drug substance; and information sufficient to support stability of the drug substance during the toxicological studies and the planned clinical studies. Reference to the current edition of the United States Pharmacopeia—National Formulary may satisfy relevant requirements in this paragraph.

(b) *Drug product.* A list of all components, which may include reasonable alternatives for inactive compounds, used in the manufacture of the investigational drug product, including both those components intended to appear in the drug product and those which may not appear but which are used in the manufacturing process, and, where applicable, the quantitative composition of the investigational drug product, including any reasonable variations that may be expected during the investigational stage; the name and address of the drug product manufacturer; a brief general description of the manufacturing and

packaging procedure as appropriate for the product; the acceptable limits and analytical methods used to assure the identity, strength, quality, and purity of the drug product; and information sufficient to assure the product's stability during the planned clinical studies. Reference to the current edition of the United States Pharmacopeia—National Formulary may satisfy certain requirements in this paragraph.

(c) A brief general description of the composition, manufacture, and control of any placebo used in a controlled clinical trial.

(d) *Labeling.* A copy of all labels and labeling to be provided to each investigator.

(e) *Environmental analysis requirements.* A claim for categorical exclusion under § 25.24 or an environmental assessment under § 25.31.

(8) *Pharmacology and toxicology information.* Adequate information about pharmacological and toxicological studies of the drug involving laboratory animals or in vitro, on the basis of which the sponsor has concluded that it is reasonably safe to conduct the proposed clinical investigations. The kind, duration, and scope of animal and other tests required varies with the duration and nature of the proposed clinical investigations. Guidelines are available from FDA that describe ways in which these requirements may be met. Such information is required to include the identification and qualifications of the individuals who evaluated the results of such studies and concluded that it is reasonably safe to begin the proposed investigations and a statement of where the investigations were conducted and where the records are available for inspection. As drug development proceeds, the sponsor is required to submit informational amendments, as appropriate, with additional information pertinent to safety.

(i) *Pharmacology and drug disposition.* A section describing the pharmacological effects and mechanism(s) of action of the drug in animals, and information on the absorption, distribution, metabolism, and excretion of the drug, if known.

(ii) *Toxicology.* (a) An integrated summary of the toxicological effects of the drug in animals and in vitro. Depending on the nature of the drug and the phase of the investigation, the description is to include the results of acute, subacute, and chronic toxicity tests; tests of the drug's effects on reproduction and the developing fetus; any special toxicity test related to the drug's particular mode of administration

or conditions of use (e.g., inhalation, dermal, or ocular toxicology); and any in vitro studies intended to evaluate drug toxicity.

(b) For each toxicology study that is intended primarily to support the safety of the proposed clinical investigation, a full tabulation of data suitable for detailed review.

(iii) For each nonclinical laboratory study subject to the good laboratory practice regulations under Part 58, a statement that the study was conducted in compliance with the good laboratory practice regulations in Part 58, or, if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(9) *Previous human experience with the investigational drug.* A summary of previous human experience known to the applicant, if any, with the investigational drug. The information is required to include the following:

(i) If the investigational drug has been investigated or marketed previously, either in the United States or other countries, detailed information about such experience that is relevant to the safety of the proposed investigation or to the investigation's rationale. If the drug has been the subject of controlled trials, detailed information on such trials that is relevant to an assessment of the drug's effectiveness for the proposed investigational use(s) should also be provided. Any published material that is relevant to the safety of the proposed investigation or to an assessment of the drug's effectiveness for its proposed investigational use should be provided in full. Published material that is less directly relevant may be supplied by a bibliography.

(ii) If the drug is a combination of drugs previously investigated or marketed, the information required under paragraph (a)(9)(i) of this section should be provided for each active drug component. However, if any component in such combination is subject to an approved marketing application or is otherwise lawfully marketed in the United States, the sponsor is not required to submit published material concerning that active drug component unless such material relates directly to the proposed investigational use (including publications relevant to component-component interaction).

(iii) If the drug has been marketed outside the United States, a list of the countries in which the drug has been marketed and a list of the countries in which the drug has been withdrawn from marketing for reasons potentially related to safety or effectiveness.

(10) *Additional information.* In certain applications, as described below,

information on special topics may be needed. Such information shall be submitted in this section as follows:

(i) *Drug dependence and abuse potential.* If the drug is a psychotropic substance or otherwise has abuse potential, a section describing relevant clinical studies and experience and studies in test animals.

(ii) *Radioactive drugs.* If the drug is a radioactive drug, sufficient data from animal or human studies to allow a reasonable calculation of radiation-absorbed dose to the whole body and critical organs upon administration to a human subject. Phase 1 studies of radioactive drugs must include studies which will obtain sufficient data for dosimetry calculations.

(iii) *Other information.* A brief statement of any other information that would aid evaluation of the proposed clinical investigations with respect to their safety or their design and potential as controlled clinical trials to support marketing of the drug.

(11) *Relevant information.* If requested by FDA, any other relevant information needed for review of the application.

(b) *Information previously submitted.* The sponsor ordinarily is not required to resubmit information previously submitted, but may incorporate the information by reference. A reference to information submitted previously must identify the file by name, reference number, volume, and page number where the information can be found. A reference to information submitted to the agency by a person other than the sponsor is required to contain a written statement that authorizes the reference and that is signed by the person who submitted the information.

(c) *Material in a foreign language.* The sponsor shall submit an accurate and complete English translation of each part of the IND that is not in English. The sponsor shall also submit a copy of each original literature publication for which an English translation is submitted.

(d) *Number of copies.* The sponsor shall submit an original and two copies of all submissions to the IND file, including the original submission and all amendments and reports.

§ 312.30 Protocol amendments.

Once an IND is in effect, a sponsor shall amend it as needed to ensure that the clinical investigations are conducted according to protocols included in the application. This section sets forth the provisions under which new protocols may be submitted and changes in previously submitted protocols may be made.

(a) *New protocol.* Whenever a sponsor intends to conduct a study that is not covered by a protocol already contained in the IND, the sponsor shall submit to FDA a protocol amendment containing the protocol for the study. Such study may begin provided two conditions are met: (1) The sponsor has submitted the protocol to FDA for its review; and (2) the protocol has been approved by the Institutional Review Board (IRB) with responsibility for review and approval of the study in accordance with the requirements of Part 56. The sponsor may comply with these two conditions in either order.

(b) *Changes in a protocol.* (1) A sponsor shall submit a protocol amendment describing any change in a Phase 1 protocol that significantly affects the safety of subjects or any change in a Phase 2 or 3 protocol that significantly affects the safety of subjects, the scope of the investigation, or the scientific quality of the study. Examples of changes requiring an amendment under this paragraph include:

(i) Any increase in drug dosage or duration of exposure of individual subjects to the drug beyond that in the current protocol, or any significant increase in the number of subjects under study.

(ii) Any significant change in the design of a protocol (such as the addition or dropping of a control group).

(iii) The addition of a new test or procedure that is intended to improve monitoring for, or reduce the risk of, a side effect or adverse event; or the dropping of a test intended to monitor safety.

(2)(i) A protocol change under paragraph (b)(1) of this section may be made provided two conditions are met:

(a) The sponsor has submitted the change to FDA for its review; and

(b) The change has been approved by the IRB with responsibility for review and approval of the study. The sponsor may comply with these two conditions in either order.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, a protocol change intended to eliminate an apparent immediate hazard to subjects may be implemented immediately provided FDA is subsequently notified by protocol amendment and the reviewing IRB is notified in accordance with § 56.104(c).

(c) *New investigator.* A sponsor shall submit a protocol amendment when a new investigator is added to carry out a previously submitted protocol, except that a protocol amendment is not required when a licensed practitioner is

added in the case of a treatment protocol under § 312.34. Once the investigator is added to the study, the investigational drug may be shipped to the investigator and the investigator may begin participating in the study. The sponsor shall notify FDA of the new investigator within 30 days of the investigator being added.

(d) *Content and format.* A protocol amendment is required to be prominently identified as such (i.e., "Protocol Amendment: New Protocol", "Protocol Amendment: Change in Protocol", or "Protocol Amendment: New Investigator"), to be serially numbered, and to contain the following:

(1)(i) In the case of a new protocol, a copy of the new protocol and a brief description of the most clinically significant differences between it and previous protocols.

(ii) In the case of a change in protocol, a brief description of the change and reference (date and number) to the submission that contained the protocol.

(iii) In the case of a new investigator, the investigator's name, the qualifications to conduct the investigation, reference to the previously submitted protocol, and all additional information about the investigator's study as is required under § 312.23(a)(6)(iii)(b).

(2) Reference, if necessary, to specific technical information in the IND or in a concurrently submitted information amendment to the IND that the sponsor relies on to support any clinically significant change in the new or amended protocol. If the reference is made to supporting information already in the IND, the sponsor shall identify by name, reference number, volume, and page number the location of the information.

(3) If the sponsor desires FDA to comment on the submission, a request for such comment and the specific questions FDA's response should address.

(e) *When submitted.* A sponsor shall submit a protocol amendment for a new protocol or a change in protocol before its implementation. Protocol amendments to add a new investigator or to provide additional information about investigators may be grouped and submitted at 30-day intervals. When several submissions of new protocols or protocol changes are anticipated during a short period, the sponsor is encouraged, to the extent feasible, to include these all in a single submission.

§312.31 Information amendments.

(a) *Requirement for information amendment.* A sponsor shall report in an information amendment essential

information on the IND that is not within the scope of a protocol amendment, IND safety reports, or annual report. Examples of information requiring an information amendment include:

(1) New toxicology, chemistry, or other technical information; or

(2) A report regarding the discontinuance of a clinical investigation.

(b) *Content and format of an information amendment.* An information amendment is required to bear prominent identification of its contents (e.g., "Information Amendment: Chemistry, Manufacturing, and Control", "Information Amendment: Pharmacology-Toxicology", "Information Amendment: Clinical"), to be numbered serially by discipline, and to contain the following:

(1) A statement of the nature and purpose of the amendment.

(2) An organized submission of the data in a format appropriate for scientific review.

(3) If the sponsor desires FDA to comment on an information amendment, a request for such comment.

(c) *When submitted.* Information amendments to the IND should be submitted as necessary but, to the extent feasible, not more than every 30 days.

§312.32 IND safety reports.

(a) *Definitions.* The following definitions of terms apply to this section:

"Associated with the use of the drug" means that there is a reasonable possibility that the experience may have been caused by the drug.

"Serious adverse experience" means any experience that suggests a significant hazard, contraindication, side effect, or precaution. With respect to human clinical experience, a serious adverse drug experience includes any experience that is fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose. With respect to results obtained from tests in laboratory animals, a serious adverse drug experience includes any experience suggesting a significant risk for human subjects, including any finding of mutagenicity, teratogenicity, or carcinogenicity.

"Unexpected adverse experience" means any adverse experience that is not identified in nature, severity, or frequency in the current investigator brochure; or, if an investigator brochure is not required, that is not identified in nature, severity, or frequency in the risk information described in the general

investigational plan or elsewhere in the current application, as amended.

(b) *Review of safety information.* The sponsor shall promptly review all information relevant to the safety of the drug obtained or otherwise received by the sponsor from any source, foreign or domestic, including information derived from clinical investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers.

(c) *IND safety reports.* (1) *Written reports.* The sponsor shall notify FDA and all participating investigators in a written IND safety report of any adverse experience associated with use of the drug that is both serious and unexpected. Such notification shall be made as soon as possible and in no event later than 10 working days after the sponsor's initial receipt of the information. Each written notification shall bear prominent identification of its contents, i.e., "IND Safety Report." Each written notification to FDA shall be transmitted to the FDA division of the Center for Drugs and Biologics which has responsibility for review of the IND.

(ii) In each written IND safety report, the sponsor shall identify all safety reports previously filed with the IND concerning a similar adverse experience, and shall analyze the significance of the adverse experience in light of the previous, similar reports.

(2) *Telephone report.* The sponsor shall also notify FDA by telephone of any unexpected fatal or life-threatening experience associated with use of the drug in the clinical studies conducted under the IND no later than 3 working days after receipt of the information. Each telephone call to FDA shall be transmitted to the FDA division of the Center for Drugs and Biologics which has responsibility for review of the IND. For purposes of this section, life-threatening means that the patient was, in the view of the investigator, at immediate (emphasis added) risk of death from the reaction as it occurred, i.e., it does not include a reaction that, had it occurred in a more serious form, might have caused death. For example, drug-induced hepatitis that resolved without evidence of hepatic failure would not be considered life-threatening even though drug-induced hepatitis can be fatal.

(3) *Reporting format or frequency.* FDA may request a sponsor to submit IND safety reports in a format or at a frequency different than that required under this paragraph. The sponsor may also propose and adopt a different reporting format or frequency if the

change is agreed to in advance by the director of the division in the Center for Drugs and Biologics which is responsible for review of the IND.

(4) A sponsor of a clinical study of a marketed drug is not required to make a safety report for any adverse experience associated with use of the drug that is not from the clinical study itself.

(d) *Followup.* (1) The sponsor shall promptly investigate all safety information received by it.

(2) Followup information to a safety report shall be submitted as soon as the relevant information is available.

(3) If the results of a sponsor's investigation show that an adverse experience not initially determined to be reportable under paragraph (c) of this section is so reportable, the sponsor shall report such experience in a safety report as soon as possible after the determination is made, but in no event longer than 10-working days.

(4) Results of a sponsor's investigation of other safety information shall be submitted, as appropriate, in an information amendment or annual report.

(e) *Disclaimer.* A safety report or other information submitted by a sponsor under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the sponsor or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse experience. A sponsor need not admit, and may deny, that the report or information submitted by the sponsor constitutes an admission that the drug caused or contributed to an adverse experience.

§ 312.33 Annual reports.

A sponsor shall within 60 days of the anniversary date that the IND went into effect, submit a brief report of the progress of the investigation that includes:

(a) *Individual study information.* A brief summary of the status of each study in progress and each study completed during the previous year. The summary is required to include the following information for each study:

(1) The title of the study (with any appropriate study identifiers such as protocol number), its purpose, a brief statement identifying the patient population, and a statement as to whether the study is completed.

(2) The total number of subjects initially planned for inclusion in the study, the number entered into the study to date, the number whose participation in the study was completed as planned, and the number who dropped out of the study for any reason.

(3) If the study has been completed, or if interim results are known, a brief description of any available study results.

(b) *Summary information.* Information obtained during the previous year's clinical and nonclinical investigations, including:

(1) A narrative or tabular summary showing the most frequent and most serious adverse experiences by body system.

(2) A summary of all IND safety reports submitted during the past year.

(3) A list of subjects who died during participation in the investigation, with the cause of death for each subject.

(4) A list of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be drug related.

(5) A brief description of what, if anything, was obtained that is pertinent to an understanding of the drug's actions, including, for example, information about dose response, information from controlled trials, and information about bioavailability.

(6) A list of the preclinical studies (including animal studies) completed or in progress during the past year and a summary of the major preclinical findings.

(7) A summary of any significant manufacturing or microbiological changes made during the past year.

(c) A description of the general investigational plan for the coming year to replace that submitted 1 year earlier. The general investigational plan shall contain the information required under § 312.23(a)(3)(iv).

(d) If the investigator brochure has been revised, a description of the revision and a copy of the new brochure.

(e) A description of any significant Phase 1 protocol modifications made during the previous year and not previously reported to the IND in a protocol amendment.

(f) A brief summary of significant foreign marketing developments with the drug during the past year, such as approval of marketing in any country or withdrawal or suspension from marketing in any country.

(g) If desired by the sponsor, a log of any outstanding business with respect to the IND for which the sponsor requests or expects a reply, comment, or meeting.

§ 312.34 Treatment use of an investigational new drug. [Reserved]

§ 312.36 Emergency use of an investigational new drug.

Need for an investigational drug may arise in an emergency situation that does not allow time for submission of an IND in accordance with § 312.23 or § 312.34. In such a case, FDA may authorize shipment of the drug for a specified use in advance of submission of an IND. A request for such authorization may be transmitted to FDA by telephone or other rapid communication means. For investigational biological drugs, the request should be directed to the Division of Biological Investigational New Drugs (HFN-823), Center for Drugs and Biologics, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-4864. For all other investigational drugs, the request for authorization should be directed to the Product Information Coordination Staff (HFN-46), Center for Drugs and Biologics, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4320. After normal working hours, eastern standard time, the request should be directed to the FDA Division of Emergency and Epidemiological Operations, 202-857-8400. Except in extraordinary circumstances, such authorization will be conditioned on the sponsor making an appropriate IND submission as soon as practicable after receiving the authorization.

§ 312.38 Withdrawal of an IND.

(a) At any time a sponsor may withdraw an effective IND without prejudice.

(b) If an IND is withdrawn, FDA shall be so notified, all clinical investigations conducted under the IND shall be ended, all current investigators notified, and all stocks of the drug returned to the sponsor or otherwise disposed of at the request of the sponsor in accordance with § 312.59.

(c) If an IND is withdrawn because of a safety reason, the sponsor shall promptly so inform FDA, all participating investigators, and all reviewing Institutional Review Boards, together with the reasons for such withdrawal.

Subpart C—Administrative Actions

§ 312.40 General requirements for use of an investigational new drug in a clinical investigation.

(a) An investigational new drug may be used in a clinical investigation if the following conditions are met:

(1) The sponsor of the investigation submits an IND for the drug to FDA; the

IND is in effect under paragraph (b) of this section; and the sponsor complies with all applicable requirements in this part and Parts 50 and 56 with respect to the conduct of the clinical investigations; and

(2) Each participating investigator conducts his or her investigation in compliance with the requirements of this part and Parts 50 and 56.

(b) An IND goes into effect:

(1) Thirty days after FDA receives the IND, unless FDA notifies the sponsor that the investigations described in the IND are subject to a clinical hold under § 312.42; or

(2) On earlier notification by FDA that the clinical investigations in the IND may begin. FDA will notify the sponsor in writing of the date it receives the IND.

(c) A sponsor may ship an investigational new drug to investigators named in the IND:

(1) Thirty days after FDA receives the IND; or

(2) On earlier FDA authorization to ship the drug.

(d) An investigator may not administer an investigational new drug to human subjects until the IND goes into effect under paragraph (b) of this section.

§ 312.41 Comment and advice on an IND.

(a) FDA may at any time during the course of the investigation communicate with the sponsor orally or in writing about deficiencies in the IND or about FDA's need for more data or information.

(b) On the sponsor's request, FDA will provide advice on specific matters relating to an IND. Examples of such advice may include advice on the adequacy of technical data to support an investigational plan, on the design of a clinical trial, and on whether proposed investigations are likely to produce the data and information that is needed to meet requirements for a marketing application.

(c) Unless the communication is accompanied by a clinical hold order under § 312.42, FDA communications with a sponsor under this section are solely advisory and do not require any modification in the planned or ongoing clinical investigations or response to the agency.

§ 312.42 Clinical holds and requests for modification.

(a) General. A clinical hold is an order issued by FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. The clinical hold order may apply to one or more of the investigations covered by an IND. When a proposed study is placed

on clinical hold, subjects may not be given the investigational drug. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug; patients already in the study should be taken off therapy involving the investigational drug unless specifically permitted by FDA in the interest of patient safety.

(b) *Grounds for imposition of clinical hold—(1) Clinical hold of a Phase 1 study under an IND.* FDA may place a proposed or ongoing Phase 1 investigation on clinical hold if it finds that:

(i) Human subjects are or would be exposed to an unreasonable and significant risk of illness or injury;

(ii) The clinical investigators named in the IND are not qualified by reason of their scientific training and experience to conduct the investigation described in the IND;

(iii) The investigator brochure is misleading, erroneous, or materially incomplete; or

(iv) The IND does not contain sufficient information required under § 312.23 to assess the risks to subjects of the proposed studies.

(2) *Clinical hold of a Phase 2 or 3 study under an IND.* FDA may place a proposed or ongoing Phase 2 or 3 investigation on clinical hold if it finds that:

(i) Any of the conditions in paragraph (b)(1)(i) through (iv) of this section apply; or

(ii) The plan or protocol for the investigation is clearly deficient in design to meet its stated objectives.

(c) *Discussion of deficiency.*

Whenever FDA concludes that a deficiency exists in a clinical investigation that may be grounds for the imposition of clinical hold FDA will, unless patients are exposed to immediate and serious risk, attempt to discuss and satisfactorily resolve the matter with the sponsor before issuing the clinical hold order.

(d) *Imposition of clinical hold.* The clinical hold order may be made by telephone or other means of rapid communication or in writing. The clinical hold order will identify the studies under the IND to which the hold applies, and will briefly explain the basis for the action. The clinical hold order will be made by or on behalf of the Division Director with responsibility for review of the IND. As soon as possible, and no more than 30 days after imposition of the clinical hold, the Division Director will provide the sponsor a written explanation of the basis for the hold.

(e) *Resumption of clinical investigations.* If, by the terms of the clinical hold order, resumption of the affected investigation is permitted without prior notification by FDA once a stated correction or modification is made, the investigation may proceed as soon as the correction or modification is made. In all other cases, an investigation may only resume after the Division Director (or the Director's designee) with responsibility for review of the IND has notified the sponsor that the investigation may proceed. In these cases resumption of the affected investigation(s) will be authorized when the sponsor corrects the deficiency(ies) previously cited or otherwise satisfied the agency that the investigation(s) can proceed. Resumption of a study may be authorized by telephone or other means of rapid communication.

(f) *Appeal.* If the sponsor disagrees with the reasons cited for the clinical hold, the sponsor may request reconsideration of the decision in accordance with § 312.48.

(g) *Conversion of IND on clinical hold to inactive status.* If all investigations covered by an IND remain on clinical hold for 1 year or more, the IND may be placed on inactive status by FDA under § 312.45.

§ 312.44 Termination.

(a) *General.* This section describes the procedures under which FDA may terminate an IND. If an IND is terminated, the sponsor shall end all clinical investigations conducted under the IND and recall or otherwise provide for the disposition of all unused supplies of the drug. A termination action may be based on deficiencies in the IND or in the conduct of an investigation under an IND. Except as provided in paragraph (d) of this section, a termination shall be preceded by a proposal to terminate by FDA and an opportunity for the sponsor to respond. FDA will, in general, only initiate an action under this section after first attempting to resolve differences informally or, when appropriate, through the clinical hold procedures described in § 312.42.

(b) *Grounds for termination—(1) Phase 1.* FDA may propose to terminate an IND during Phase 1 if it finds that:

(i) Human subjects would be exposed to an unreasonable and significant risk of illness or injury.

(ii) The IND does not contain sufficient information required under § 312.23 to assess the safety to subjects of the clinical investigations.

(iii) The methods, facilities, and controls used for the manufacturing, processing, and packing of the

investigational drug are inadequate to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for subject safety.

(iv) The clinical investigations are being conducted in a manner substantially different than that described in the protocols submitted in the IND.

(v) The drug is being promoted or distributed for commercial purposes not justified by the requirements of the investigation or permitted by § 312.7.

(vi) The IND, or any amendment or report to the IND, contains an untrue statement of a material fact or omits material information required by this part.

(vii) The sponsor fails promptly to investigate and inform the Food and Drug Administration and all investigators of serious and unexpected adverse experiences in accordance with § 312.32 or fails to make any other report required under this part.

(viii) The sponsor fails to submit an accurate annual report of the investigations in accordance with § 312.33.

(ix) The sponsor fails to comply with any other applicable requirement of this part, Part 50, or Part 56.

(x) The IND has remained on inactive status for 5 years or more.

(2) *Phase 2 or 3.* FDA may propose to terminate an IND during Phase 2 or Phase 3 if FDA finds that:

(i) Any of the conditions in paragraph (b)(1)(i) through (x) of this section apply; or

(ii) The investigational plan or protocol(s) is not reasonable as a bona fide scientific plan to determine whether or not the drug is safe and effective for use; or

(iii) There is convincing evidence that the drug is not effective for the purpose for which it is being investigated.

(3) FDA may propose to terminate a treatment IND if it finds that:

(i) Any of the conditions in paragraphs (b)(1)(i) through (x) of this section apply; or

(ii) Any of the conditions in § 312.42(b)(3) apply.

(c) *Opportunity for sponsor response.*

(1) If FDA proposes to terminate an IND, FDA will notify the sponsor in writing, and invite correction or explanation within a period of 30 days.

(2) On such notification, the sponsor may provide a written explanation or correction or may request a conference with FDA to provide the requested explanation or correction. If the sponsor does not respond to the notification within the allocated time, the IND shall be terminated.

(3) If the sponsor responds but FDA does not accept the explanation or correction submitted, FDA shall inform the sponsor in writing of the reason for the nonacceptance and provide the sponsor with an opportunity for a regulatory hearing before FDA under Part 16 on the question of whether the IND should be terminated. The sponsor's request for a regulatory hearing must be made within 10 days of the sponsor's receipt of FDA's notification of nonacceptance.

(d) *Immediate termination of IND.* Notwithstanding paragraphs (a) through (c) of this section, if at any time FDA concludes that continuation of the investigation presents an immediate and substantial danger to the health of individuals, the agency shall immediately, by written notice to the sponsor from the Director of the Center for Drugs and Biologics, terminate the IND. An IND so terminated is subject to reinstatement by the Director on the basis of additional submissions that eliminate such danger. If an IND is terminated under this paragraph, the agency will afford the sponsor an opportunity for a regulatory hearing under Part 16 on the question of whether the IND should be reinstated.

§ 312.45 Inactive status.

(a) If no subjects are entered into clinical studies for a period of 2 years or more under an IND, or if all investigations under an IND remain on clinical hold for 1 year or more, the IND may be placed by FDA on inactive status. This action may be taken by FDA either on request of the sponsor or on FDA's own initiative. If FDA seeks to act on its own initiative under this section, it shall first notify the sponsor in writing of the proposed inactive status. Upon receipt of such notification, the sponsor shall have 30 days to respond as to why the IND should continue to remain active.

(b) If an IND is placed on inactive status, all investigators shall be so notified and all stocks of the drug shall be returned or otherwise disposed of in accordance with § 312.59.

(c) A sponsor is not required to submit annual reports to an IND on inactive status. An inactive IND is, however, still in effect for purposes of the public disclosure of data and information under § 312.130.

(d) A sponsor who intends to resume clinical investigation under an IND placed on inactive status shall submit a protocol amendment under § 312.30 containing the proposed general investigational plan for the coming year and appropriate protocols. If the protocol amendment relies on

information previously submitted, the plan shall reference such information. Additional information supporting the proposed investigation, if any, shall be submitted in an information amendment. Notwithstanding the provisions of § 312.30, clinical investigations under an IND on inactive status may only resume (1) 30 days after FDA receives the protocol amendment, unless FDA notifies the sponsor that the investigations described in the amendment are subject to a clinical hold under § 312.42, or (2) on earlier notification by FDA that the clinical investigations described in the protocol amendment may begin.

(e) An IND that remains on inactive status for 5 years or more may be terminated under § 312.44.

§ 312.47 Meetings.

(a) *General.* Meetings between a sponsor and the agency are frequently useful in resolving questions and issues raised during the course of a clinical investigation. FDA encourages such meetings to the extent that they aid in the evaluation of the drug and in the solution of scientific problems concerning the drug, to the extent that FDA's resources permit. The general principle underlying the conduct of such meetings is that there should be free, full, and open communication about any scientific or medical question that may arise during the clinical investigation. These meetings shall be conducted and documented in accordance with Part 10.

(b) *"End-of-Phase 2" meetings and meetings held before submission of a marketing application.* At specific times during the drug investigation process, meetings between FDA and a sponsor can be especially helpful in minimizing wasteful expenditures of time and money and thus in speeding the drug development and evaluation process. In particular, FDA has found that meetings at the end of Phase 2 of an investigation (end-of-Phase 2 meetings) are of considerable assistance in planning later studies and that meetings held near completion of Phase 3 and before submission of a marketing application ("pre-NDA" meetings) are helpful in developing methods of presentation and submission of data in the marketing application that facilitate review and allow timely FDA response.

(1) *End-of-Phase 2 meetings—(i) Purpose.* The purpose of an end-of-Phase 2 meeting is to determine the safety of proceeding to Phase 3, to evaluate the Phase 3 plan and protocols, and to identify any additional information necessary to support a

marketing application for the uses under investigation.

(ii) *Eligibility for meeting.* While the end-of-Phase 2 meeting is designed primarily for IND's involving new molecular entities or major new uses of marketed drugs, a sponsor of any IND may request and obtain an end-of-Phase 2 meeting.

(iii) *Timing.* To be most useful to the sponsor, end-of-Phase 2 meetings should be held before major commitments of effort and resources to specific Phase 3 tests are made. The scheduling of an end-of-Phase 2 meeting is not, however, intended to delay the transition of an investigation from Phase 2 to Phase 3.

(iv) *Advance information.* At least 1 month in advance of an end-of-Phase 2 meeting, the sponsor should submit background information on the sponsor's plan for Phase 3, including summaries of the Phase 1 and 2 investigations, the specific protocols for Phase 3 clinical studies, plans for any additional nonclinical studies, and, if available, tentative labeling for the drug. The recommended contents of such a submission are described more fully in FDA Staff Manual Guide 4850.6 that is publicly available under FDA's public information regulations in Part 20.

(v) *Conduct of meeting.* Arrangements for an end-of-Phase 2 meeting are to be made with the division in FDA's Center for Drugs and Biologics which is responsible for review of the IND. The meeting will be scheduled by FDA at a time convenient to both FDA and the sponsor. Both the sponsor and FDA may bring consultants to the meeting. The meeting should be directed primarily at establishing agreement between FDA and the sponsor of the overall plan for Phase 3 and the objectives and design of particular studies. The adequacy of technical information to support Phase 3 studies and/or a marketing application may also be discussed. Agreements reached at the meeting on these matters will be recorded in minutes of the conference that will be taken by FDA in accordance with § 10.65 and provided to the sponsor. The minutes along with any other written material provided to the sponsor will serve as a permanent record of any agreements reached. Barring a significant scientific development that requires otherwise, studies conducted in accordance with the agreement shall be presumed to be sufficient in objective and design for the purpose of obtaining marketing approval for the drug.

(2) *"Pre-NDA" meetings.* FDA has found that delays associated with the initial review of a marketing application may be reduced by exchanges of information about a proposed marketing

application. The primary purpose of this kind of exchange is to uncover any major unresolved problems, to identify those studies that the sponsor is relying on as adequate and well-controlled to establish the drug's effectiveness, to acquaint FDA reviewers with the general information to be submitted in the marketing application (including technical information), to discuss appropriate methods for statistical analysis of the data, and to discuss the best approach to the presentation and formatting of data in the marketing application. Arrangements for such a meeting are to be initiated by the sponsor with the division responsible for review of the IND. To permit FDA to provide the sponsor with the most useful advice on preparing a marketing application, the sponsor should submit to FDA's reviewing division at least 1 month in advance of the meeting the following information:

- (i) A brief summary of the clinical studies to be submitted in the application.
- (ii) A proposed format for organizing the submission, including methods for presenting the data.
- (iii) Any other information for discussion at the meeting.

§ 312.48 Dispute resolution.

(a) *General.* The Food and Drug Administration is committed to resolving differences between sponsors and FDA reviewing divisions with respect to requirements for IND's as quickly and amicably as possible through the cooperative exchange of information and views.

(b) *Administrative and procedural issues.* When administrative or procedural disputes arise, the sponsor should first attempt to resolve the matter with the division in FDA's Center for Drugs and Biologics which is responsible for review of the IND, beginning with the consumer safety officer assigned to the application. If the dispute is not resolved, the sponsor may raise the matter with the person designated as ombudsman, whose function shall be to investigate what has happened and to facilitate a timely and equitable resolution. Appropriate issues to raise with the ombudsman include resolving difficulties in scheduling meetings and obtaining timely replies to inquiries. Further details on this procedure are contained in FDA Staff Manual Guide 4820.7 that is publicly available under FDA's public information regulations in Part 20.

(c) *Scientific and medical disputes.* (1) When scientific or medical disputes arise during the drug investigation process, sponsors should discuss the

matter directly with the responsible reviewing officials. If necessary, sponsors may request a meeting with the appropriate reviewing officials and management representatives in order to seek a resolution. Requests for such meetings shall be directed to the director of the division in FDA's Center for Drugs and Biologics which is responsible for review of the IND. FDA will make every attempt to grant requests for meetings that involve important issues and that can be scheduled at mutually convenient times.

(2) The "end-of-Phase 2" and "pre-NDA" meetings described in § 312.47(b) will also provide a timely forum for discussing and resolving scientific and medical issues on which the sponsor disagrees with the agency.

(3) In requesting a meeting designed to resolve a scientific or medical dispute, applicants may suggest that FDA seek the advice of outside experts, in which case FDA may, in its discretion, invite to the meeting one or more of its advisory committee members or other consultants, as designated by the agency. Applicants may rely on, and may bring to any meeting, their own consultants. For major scientific and medical policy issues not resolved by informal meetings, FDA may refer the matter to one of its standing advisory committees for its consideration and recommendations.

Subpart D—Responsibilities of Sponsors and Investigators

§ 312.50 General responsibilities of sponsors.

Sponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND, maintaining an effective IND with respect to the investigations, and ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. Additional specific responsibilities of sponsors are described elsewhere in this part.

§ 312.52 Transfer of obligations to a contract research organization.

(a) A sponsor may transfer responsibility for any or all of the obligations set forth in this part to a contract research organization. Any such transfer shall be described in writing. If not all obligations are

transferred, the writing is required to describe each of the obligations being assumed by the contract research organization. If all obligations are transferred, a general statement that all obligations have been transferred is acceptable. Any obligation not covered by the written description shall be deemed not to have been transferred.

(b) A contract research organization that assumes any obligation of a sponsor shall comply with the specific regulations in this chapter applicable to this obligation and shall be subject to the same regulatory action as a sponsor for failure to comply with any obligation assumed under these regulations. Thus, all references to "sponsor" in this part apply to a contract research organization to the extent that it assumes one or more obligations of the sponsor.

§ 312.53 Selecting investigators and monitors.

(a) *Selecting investigators.* A sponsor shall select only investigators qualified by training and experience as appropriate experts to investigate the drug.

(b) *Control of drug.* A sponsor shall ship investigational new drugs only to investigators participating in the investigation.

(c) *Obtaining information from the investigator.* Before permitting an investigator to begin participation in an investigation, the sponsor shall obtain the following:

(1) A signed investigator statement (Form FDA-1572) containing:

(i) The name and address of the investigator;

(ii) The name and code number, if any, of the protocol(s) in the IND identifying the study(ies) to be conducted by the investigator;

(iii) The name and address of any medical school, hospital, or other research facility where the clinical investigation(s) will be conducted;

(iv) The name and address of any clinical laboratory facilities to be used in the study;

(v) The name and address of the IRB that is responsible for review and approval of the study(ies);

(vi) A commitment by the investigator that he or she:

(a) Will conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, the rights, or welfare of subjects;

(b) Will comply with all requirements regarding the obligations of clinical investigators and all other pertinent requirements in this part;

(c) Will personally conduct or supervise the described investigation(s);

(d) Will inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent and institutional review board review and approval are met;

(e) Will report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with § 312.64;

(f) Has read and understands the information in the investigator's brochure, including the potential risks and side effects of the drug; and

(g) Will ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

(vii) A commitment by the investigator that, for an investigation subject to an institutional review requirement under Part 56, an IRB that complies with the requirements of that part will be responsible for the initial and continuing review and approval of the clinical investigation and that the investigator will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others, and will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to the human subjects.

(viii) A list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s).

(2) *Curriculum vitae.* A curriculum vitae or other statement of qualifications of the investigator showing the education, training, and experience that qualifies the investigator as an expert in the clinical investigation of the drug for the use under investigation.

(3) *Clinical protocol.* (i) For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

(ii) For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a

description of case report forms to be used.

(d) *Selecting monitors.* A sponsor shall select a monitor qualified by training and experience to monitor the progress of the investigation.

§ 312.55 Informing investigators.

(a) Before the investigation begins, a sponsor (other than a sponsor-investigator) shall give each participating clinical investigator an investigator brochure containing the information described in § 312.23(a)(5).

(b) The sponsor shall, as the overall investigation proceeds, keep each participating investigator informed of new observations discovered by or reported to the sponsor on the drug, particularly with respect to adverse effects and safe use. Such information may be distributed to investigators by means of periodically revised investigator brochures, reprints or published studies, reports or letters to clinical investigators, or other appropriate means. Important safety information is required to be relayed to investigators in accordance with § 312.32.

§ 312.56 Review of ongoing investigations.

(a) The sponsor shall monitor the progress of all clinical investigations being conducted under its IND.

(b) A sponsor who discovers that an investigator is not complying with the signed agreement (Form FDA-1572), the general investigational plan, or the requirements of this part or other applicable parts shall promptly either secure compliance or discontinue shipments of the investigational new drug to the investigator and end the investigator's participation in the investigation. If the investigator's participation in the investigation is ended, the sponsor shall require that the investigator dispose of or return the investigational drug in accordance with the requirements of § 312.59 and shall notify FDA.

(c) The sponsor shall review and evaluate the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator. The sponsors shall make such reports to FDA regarding information relevant to the safety of the drug as are required under § 312.32. The sponsor shall make annual reports on the progress of the investigation in accordance with § 312.33.

(d) A sponsor who determines that its investigational drug presents an unreasonable and significant risk to subjects shall discontinue those

investigations that present the risk, notify FDA, all institutional review boards, and all investigators who have at any time participated in the investigation of the discontinuance, assure the disposition of all stocks of the drug outstanding as required by § 312.59, and furnish FDA with a full report of the sponsor's actions. The sponsor shall discontinue the investigation as soon as possible, and in no event later than 5 working days after making the determination that the investigation should be discontinued. Upon request, FDA will confer with a sponsor on the need to discontinue an investigation.

§ 312.57 Recordkeeping and record retention.

(a) A sponsor shall maintain adequate records showing the receipt, shipment, or other disposition of the investigational drug. These records are required to include, as appropriate, the name of the investigator to whom the drug is shipped, and the date, quantity, and batch or code mark of each such shipment.

(b) A sponsor shall retain the records and reports required by this part for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified.

§ 312.58 Inspection of sponsor's records and reports.

(a) *FDA inspection.* A sponsor shall upon request from any properly authorized officer or employee of the Food and Drug Administration, at reasonable times, permit such officer or employee to have access to and copy and verify any records and reports relating to a clinical investigation conducted under this part. Upon written request by FDA, the sponsor shall submit the records or reports (or copies of them) to FDA. The sponsor shall discontinue shipments of the drug to any investigator who has failed to maintain or make available records or reports of the investigation as required by this part.

(b) *Controlled substances.* If an investigational new drug is a substance listed in any schedule of the Controlled Substances Act (21 U.S.C. 801; 21 CFR Part 1308), records concerning shipment, delivery, receipt, and disposition of the drug, which are required to be kept under this part or other applicable parts of this chapter shall, upon the request of a properly authorized employee of the Drug Enforcement Administration of the U.S. Department of Justice, be made

available by the investigator or sponsor to whom the request is made, for inspection and copying. In addition, the sponsor shall assure that adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

§ 312.59 Disposition of unused supply of investigational drug.

The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug. The sponsor shall maintain written records of any disposition of the drug in accordance with § 312.57.

§ 312.60 General responsibilities of investigators.

An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation. An investigator shall, in accordance with the provisions of Part 50, obtain the informed consent of each human subject to whom the drug is administered, except as provided in § 50.23. Additional specific responsibilities of clinical investigators are set forth in this part and in Parts 50 and 56.

§ 312.61 Control of the investigational drug.

An investigator shall administer the drug only to subjects under the investigator's personal supervision or under the supervision of a subinvestigator responsible to the investigator. The investigator shall not supply the investigational drug to any person not authorized under this part to receive it.

§ 312.62 Investigator recordkeeping and record retention.

(a) *Disposition of drug.* An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return

the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under § 312.59.

(b) *Case histories.* An investigator is required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the investigation on each individual treated with the investigational drug or employed as a control in the investigation.

(c) *Record retention.* An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

§ 312.64 Investigator reports.

(a) *Progress reports.* The investigator shall furnish all reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained. The sponsor is required under § 312.33 to submit annual reports to FDA on the progress of the clinical investigations.

(b) *Safety reports.* An investigator shall promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator shall report the adverse effect immediately.

(c) *Final report.* An investigator shall provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.

§ 312.66 Assurance of IRB review.

An investigator shall assure that an IRB that complies with the requirements set forth in Part 56 will be responsible for the initial and continuing review and approval of the proposed clinical study. The investigator shall also assure that he or she will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risk to human subjects or others, and that he or she will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

§ 312.68 Inspection of Investigator's records and reports.

An investigator shall upon request from any properly authorized officer or employee of FDA, at reasonable times,

permit such officer or employee to have access to, and copy and verify any records or reports made by the investigator pursuant to § 312.62. The investigator is not required to divulge subject names unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.

§ 312.69 Handling of controlled substances.

If the investigational drug is subject to the Controlled Substances Act, the investigator shall take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

§ 312.70 Disqualification of a clinical investigator.

(a) If FDA has information indicating that an investigator has repeatedly or deliberately failed to comply with the requirements of this part, Part 50, or Part 56, or has submitted to the sponsor false information in any required report, the Center for Drugs and Biologics will furnish the investigator written notice of the matter complained of and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered but not accepted by the Center for Drugs and Biologics, the investigator will be given an opportunity for a regulatory hearing under Part 16 on the question of whether the investigator is entitled to receive investigational new drugs.

(b) After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the requirements of this part, Part 50, or Part 56, or has deliberately or repeatedly submitted false information to the sponsor in any required report, the Commissioner will notify the investigator and the sponsor of any investigation in which the investigator has been named as a participant that the investigator is not entitled to receive investigational drugs. The notification will provide a statement of basis for such determination.

(c) Each IND and each approved application submitted under Part 314 containing data reported by an

investigator who has been determined to be ineligible to receive investigational drugs will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval of any marketing application.

(d) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, the Commissioner will notify the sponsor who shall have an opportunity for a regulatory hearing under Part 16. If a danger to the public health exists, however, the Commissioner shall terminate the IND immediately and notify the sponsor of the determination. In such case, the sponsor shall have an opportunity for a regulatory hearing before FDA under Part 16 on the question of whether the IND should be reinstated.

(e) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued approval of the drug product for which the data were submitted cannot be justified, the Commissioner will proceed to withdraw approval of the drug product in accordance with the applicable provisions of the act.

(f) An investigator who has been determined to be ineligible to receive investigational drugs may be reinstated as eligible when the Commissioner determines that the investigator has presented adequate assurances that the investigator will employ investigational drugs solely in compliance with the provisions of this part and of Parts 50 and 56.

Subpart E—Miscellaneous

§ 312.110 Import and export requirements.

(a) *Imports.* An investigational new drug offered for import into the United States complies with the requirements of this part if it is subject to an IND that is in effect for it under § 312.40 and: (1) The consignee in the United States is the sponsor of the IND; (2) the consignee is a qualified investigator named in the IND; or (3) the consignee is the domestic agent of a foreign sponsor, is responsible for the control and distribution of the investigational drug, and the IND identifies the consignee and describes what, if any, actions the consignee will take with respect to the investigational drug.

(b) *Exports.* An investigational new drug intended for export from the United

States complies with the requirements of this part as follows:

(1) If an IND is in effect for the drug under § 312.40 and each person who receives the drug is an investigator named in the application; or

(2) If FDA authorizes shipment of the drug for use in a clinical investigation. Authorization may be obtained as follows:

(i) Through submission to the International Affairs Staff (HFY-50), Associate Commissioner for Health Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, of a written request from the person that seeks to export the drug. A request must provide adequate information about the drug to satisfy FDA that the drug is appropriate for the proposed investigational use in humans, that the drug will be used for investigational purposes only, and that the drug may be legally used by that consignee in the importing country for the proposed investigational use. The request shall specify the quantity of the drug to be shipped per shipment and the frequency of expected shipments. If FDA authorizes exportation under this paragraph, the agency shall concurrently notify the government of the importing country of such authorization.

(ii) Through submission to the International Affairs Staff (HFY-50), Associate Commissioner for Health Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, of a formal request from an authorized official of the government of the country to which the drug is proposed to be shipped. A request must specify that the foreign government has adequate information about the drug and the proposed investigational use, that the drug will be used for investigational purposes only, and that the foreign government is satisfied that the drug may legally be used by the intended consignee in that country. Such a request shall specify the quantity of drug to be shipped per shipment and the frequency of expected shipments.

(iii) Authorization to export an investigational drug under paragraph (b)(2)(i) or (ii) of this section may be revoked by FDA if the agency finds that the conditions underlying its authorization are not longer met.

(3) This paragraph applies only where the drug is to be used for the purpose of clinical investigation.

(4) This paragraph does not apply to the export of an antibiotic drug product shipped in accordance with the provisions of section 801(d) of the act.

(5) This paragraph does not apply to the export of new drugs (including

biological products) approved for export under section 802 of the act or section 351(h)(1)(A) of the Public Health Service Act.

§ 312.120 Foreign clinical studies not conducted under an IND.

(a) *Introduction.* This section describes the criteria for acceptance by FDA of foreign clinical studies not conducted under an IND. In general, FDA accepts such studies provided they are well designed, well conducted, performed by qualified investigators, and conducted in accordance with ethical principles acceptable to the world community. Studies meeting these criteria may be utilized to support clinical investigations in the United States and/or marketing approval. Marketing approval of a new drug or antibiotic drug based solely on foreign clinical data is governed by § 314.106.

(b) *Data submissions.* A sponsor who wishes to rely on a foreign clinical study to support an IND or to support an application for marketing approval shall submit to FDA the following information:

(1) A description of the investigator's qualifications;

(2) A description of the research facilities;

(3) A detailed summary of the protocol and results of the study, and, should FDA request, case records maintained by the investigator or additional background data such as hospital or other institutional records;

(4) A description of the drug substance and drug product used in the study, including a description of components, formulation, specifications, and bioavailability of the specific drug product used in the clinical study, if available; and

(5) If the study is intended to support the effectiveness of a drug product, information showing that the study is adequate and well controlled under § 314.126.

(c) *Conformance with ethical principles.* (1) Foreign clinical research is required to have been conducted in accordance with the ethical principles stated in the "Declaration of Helsinki" (see paragraph (c)(4) of this section) or the laws and regulations of the country in which the research was conducted, whichever represents the greater protection of the individual.

(2) For each foreign clinical study submitted under this section, the sponsor shall explain how the research conformed to the ethical principles contained in the "Declaration of Helsinki" or the foreign country's standards, whichever were used. If the foreign country's standards were used,

the sponsor shall explain in detail how those standards differ from the "Declaration of Helsinki" and how they offer greater protection.

(3) When the research has been approved by an independent review committee, the sponsor shall submit to FDA documentation of such review and approval, including the names and qualifications of the members of the committee. In this regard, a "review committee" means a committee composed of scientists and, where practicable, individuals who are otherwise qualified (e.g., other health professionals or laymen). The investigator may not vote on any aspect of the review of his or her protocol by a review committee.

(4) The "Declaration of Helsinki" states as follows:

Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects

I. Basic Principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publications.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the doctor should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical Research Combined With Professional Care (Clinical Research)

1. In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, reestablishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient—including those of a control group, if any—should be assured of the best proven diagnostic and therapeutic methods.

4. The refusal of the patient to participate in a study must never interfere with the doctor-patient relationship.

5. If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I, 2).

6. The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-Therapeutic Biomedical Research Involving Human Subjects (Non-Clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain

the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers—either healthy persons or patients for whom the experimental design is not related to the patient's illness.

3. The investigator or the team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

§ 312.130 Availability for public disclosure of data and information in an IND.

(a) The existence of an investigational new drug application will not be disclosed by FDA unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an investigational new drug application for a new drug or antibiotic drug will be handled in accordance with the provisions established in § 314.430 for the confidentiality of data and information in applications submitted in Part 314. The availability for public disclosure of all data and information in an investigational new drug application for a biological product will be governed by the provisions of §§ 601.50 and 601.51.

(c) Notwithstanding the provisions of § 314.430, FDA shall disclose upon request to an individual to whom an investigational new drug has been given a copy of any IND safety report relating to the use in the individual.

§ 312.140 Address for correspondence.

(a) Except as provided in paragraph (b) of this section, a sponsor shall send an initial IND submission to the Central Document Room, Center for Drugs and Biologics, Food and Drug Administration, Park Bldg., Rm. 214, 12420 Parklawn Dr., Rockville, MD 20852. On receiving the IND, FDA will inform the sponsor which one of the divisions in the Center for Drugs and Biologics is responsible for the IND. Amendments, reports, and other correspondence relating to matters covered by the IND should be directed to the appropriate division. The outside wrapper of each submission shall state what is contained in the submission, for example, "IND Application", "Protocol Amendment", etc.

(b) Applications for the products listed below should be submitted to the Office of Biologics Research and Review (HFN-823), Center for Drugs and Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205: (1) Products

subject to the licensing provisions of the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended (42 U.S.C. 201 et seq.)) or subject to Part 600; (2) ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components; (3) urokinase products; (4) plasma volume expanders and hydroxyethyl starch for leukapheresis; and (5) coupled antibodies, i.e., products that consist of an antibody component coupled with a drug or radionuclide component in which both components provide a pharmacological effect but the biological component determines the site of action.

(c) All correspondence relating to biological products for human use which are also radioactive drugs shall be submitted to the Division of Oncology and Radiopharmaceutical Drug Products (HFN-150), Office of Drug Research and Review, Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, except that applications for coupled antibodies shall be submitted in accordance with paragraph (b) of this section.

(d) All correspondence relating to export of an investigational drug under § 312.110(b)(2) shall be submitted to the International Affairs Staff (HFY-50), Office of Health Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 312.145 Guidelines.

(a) FDA has made available guidelines under § 10.90(b) to help persons to comply with certain requirements of this part.

(b) The Center for Drugs and Biologics maintains a list of guidelines that apply to the Center's regulations. The list states how a person can obtain a copy of each guideline. A request for a copy of the list should be directed to the Legislative, Professional, and Consumer Affairs Branch (HFN-360), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Subpart F—Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests

§ 312.160 Drugs for investigational use in laboratory research animals or in vitro tests.

(a) *Authorization to ship.* (1)(i) A person may ship a drug intended solely for tests in vitro or in animals used only for laboratory research purposes if it is labeled as follows:

CAUTION: Contains a new drug for investigational use only in laboratory

research animals, or for tests in vitro. Not for use in humans.

(ii) A person may ship a biological product for investigational in vitro diagnostic use that is listed in § 312.2(b)(2)(ii) if it is labeled as follows:

CAUTION: Contains a biological product for investigational in vitro diagnostic tests only.

(2) A person shipping a drug under paragraph (a) of this section shall use due diligence to assure that the consignee is regularly engaged in conducting such tests and that the shipment of the new drug will actually be used for tests in vitro or in animals used only for laboratory research.

(3) A person who ships a drug under paragraph (a) of this section shall maintain adequate records showing the name and post office address of the expert to whom the drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery. Records of shipments under paragraph (a)(1)(i) of this section are to be maintained for a period of 2 years after the shipment. Records and reports of data and shipments under paragraph (a)(1)(ii) of this section are to be maintained in accordance with § 312.57(b). The person who ships the drug shall upon request from any properly authorized officer or employee of the Food and Drug Administration, at reasonable times, permit such officer or employee to have access to and copy and verify records required to be maintained under this section.

(b) *Termination of authorization to ship.* FDA may terminate authorization to ship a drug under this section if it finds that:

(1) The sponsor of the investigation has failed to comply with any of the conditions for shipment established under this section; or

(2) The continuance of the investigation is unsafe or otherwise contrary to the public interest or the drug is used for purposes other than bona fide scientific investigation. FDA will notify the person shipping the drug of its finding and invite immediate correction. If correction is not immediately made, the person shall have an opportunity for a regulatory hearing before FDA pursuant to Part 16.

(c) *Disposition of unused drug.* The person who ships the drug under paragraph (a) of this section shall assure the return of all unused supplies of the drug from individual investigators whenever the investigation discontinues or the investigation is terminated. The person who ships the drug may authorize in writing alternative

disposition of unused supplies of the drug provided this alternative disposition does not expose humans to risks from the drug, either directly or indirectly (e.g., through food-producing animals). The shipper shall maintain records of any alternative disposition.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

2. The authority citation for 21 CFR Part 314 continues to read as follows:

Authority: Secs. 501, 502, 503, 505, 506, 507, 701, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 351, 352, 353, 355, 356, 357, 371); 21 CFR 5.10, 5.11.

3. In § 314.50 by adding new paragraph (d)(5) (x) and (xi) to read as follows:

§ 314.50 Content and format of an application.

(d) * * *

(5) * * *

(x) If a sponsor has transferred any obligations for the conduct of any clinical study to a contract research organization, a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred. If all obligations governing the conduct of the study have been transferred, a general statement of this transfer—in lieu of a listing of the specific obligations transferred—may be submitted.

(xi) If original subject records were audited or reviewed by the sponsor in the course of monitoring any clinical study to verify the accuracy of the case reports submitted to the sponsor, a list identifying each clinical study so audited or reviewed.

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

4. The authority citation for 21 CFR Part 511 continues to read as follows:

Authority: Secs. 406, 408, 409, 501, 502, 503, 505, 506, 507, 510, 512–516, 518–520, 601, 701, 706, and 801, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511–517 as amended, 72 Stat. 1785–1788 as amended, 74 Stat. 399–407 as amended, 76 Stat. 794 as amended, 82 Stat. 343–351, 90 Stat. 539–574 (21 U.S.C. 346, 346a, 348, 351, 352, 353, 355, 356, 357, 360, 360b–360f, 360h–360i, 371, 376); secs. 215, 301, 351, 354–360F, 58 Stat. 690, 702 as amended, 82 Stat.

1173–1186 as amended (42 U.S.C. 216, 241, 262, 263b–263n).

5. In § 511.1 by revising paragraph (c)(2) and by adding new paragraphs (b)(4) (vi) and (f), to read as follows:

§ 511.1 New animal drugs for investigational use exempt from section 512(a) of the act.

(b) * * *

(4) * * *

(vi) If a sponsor has transferred any obligations for the conduct of any clinical study to a contract research organization, a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred. If all obligations governing the conduct of the study have been transferred, a general statement of this transfer—in lieu of a listing of the specific obligations transferred—may be submitted.

(c) * * *

(2) If, after evaluating all available information, including any explanation presented by the investigator, the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the conditions of the exempting regulations in this section or has repeatedly or deliberately submitted false information to the sponsor of an investigation, the Commissioner will notify the investigator and the sponsor of any investigation in which he has been named as a participant that the investigator is not entitled to receive investigational use new animal drugs with a statement of the basis for such determination.

(f) Contract research organizations.

(1) For purposes of this part and Part 514, "contract research organization" means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.

(2) A sponsor may transfer responsibility for any or all of the obligations set forth in this part to a contract research organization. Any such transfer shall be in writing and, if not all obligations are transferred, shall describe each of the obligations being assumed by the contract research organization. If all obligations are transferred, a general statement that all

obligations have been transferred is acceptable. Any obligation not covered by the written description shall be deemed not to have been transferred.

(3) A contract research organization that assumes any obligation of a sponsor shall comply with the specific regulations in this chapter applicable to this obligation and shall be subject to the same regulatory action as a sponsor for failure to comply with any obligation assumed under these regulations. Thus, all references to "sponsor" in this part apply to a contract research organization to the extent that it assumes one or more obligations of the sponsor.

PART 514—NEW ANIMAL DRUG APPLICATIONS

6. The authority citation for 21 CFR Part 514 continues to read as follows:

Authority: Secs. 512 (i), (n), 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b (i), (n), 371(a)); 21 CFR 5.10, 5.11.

7. In § 514.1 by adding new paragraph (b)(8)(viii) and (ix), to read as follows:

§ 514.1 Applications.

(b) * * *

(8) * * *

(viii) If a sponsor has transferred any obligations for the conduct of any clinical study to a contract research organization, the application is required to include a statement containing the name and address of the contract research organization, identifying the clinical study, and listing the obligations transferred. If all obligations governing the conduct of the study have been transferred, a general statement of this transfer—in lieu of a listing of the specific obligations transferred—may be submitted.

(ix) If original subject records were audited or reviewed by the sponsor in the course of monitoring any clinical study to verify the accuracy of the case reports submitted to the sponsor, a list identifying each clinical study so audited or reviewed.

Dated: March 16, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

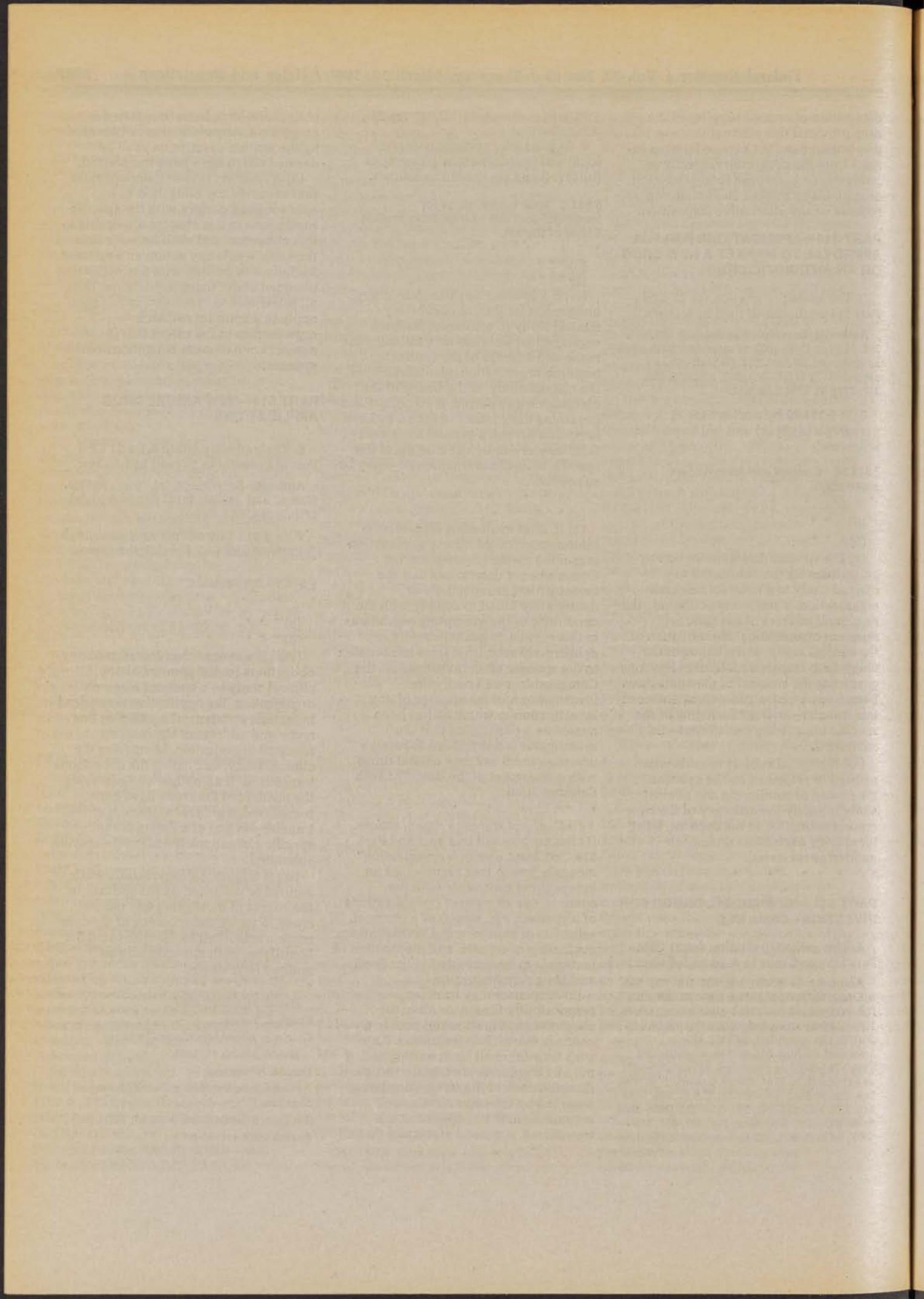
Dated: March 16, 1987.

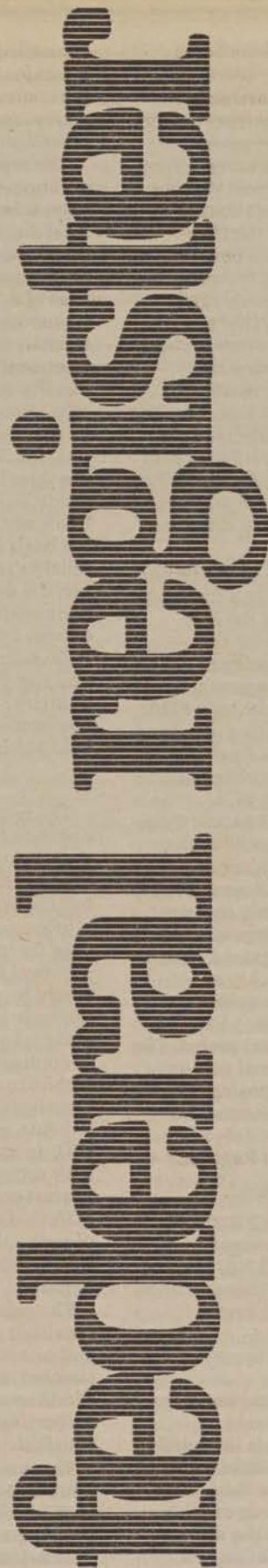
Don M. Newman,

Acting Secretary of Health and Human Services.

[FR Doc. 87–6064 Filed 3–18–87; 12:05 pm]

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Thursday
March 19, 1987

Part VIII

**Department of
Health and Human
Services**

Food and Drug Administration

21 CFR Part 312

**Investigational New Drug, Antibiotic, and
Biological Drug Product Regulations;
Treatment, Use, and Sale; Reproposed
Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 312**

(Docket No. 82N-0394)

Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale**AGENCY:** Food and Drug Administration.**ACTION:** Reproposed rule.

SUMMARY: The Food and Drug Administration (FDA) is reproposing procedures to make investigational new drugs available to desperately ill patients before general marketing begins. These procedures are intended to facilitate the availability of promising new drugs to patients as early in the drug development process as possible, and would apply to patients with immediately life-threatening or other serious diseases for which no satisfactory alternative therapies exist. The procedures for immediately life-threatening diseases would apply, for example, to advanced cases of Acquired Immune Deficiency Syndrome (AIDS) and certain uncontrollable cardiac arrhythmias, while the procedures for other serious diseases would apply, for example, to Alzheimer's and multiple sclerosis. FDA is also reproposing conditions under which drug manufacturers may sell investigational new drug products. With the revolution in biotechnology, it is important to recognize the need to provide sufficient incentives for the rapid development of drug and biological agents. Accordingly, the new procedures would allow sale of drugs, when no satisfactory alternative therapy is available, when the drugs are provided for treatment use to large numbers of patients prior to general marketing.

FDA is reproposing these issues for public comment. While these issues have been aired at great length and have received substantial analysis, FDA, in an abundance of caution and with the desire to have all groups have the opportunity for full participation, is undertaking this extra action.

DATE: Written comments by April 20, 1987.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Steven H. Unger, Center for Drugs and Biologics (HFN-362), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 9, 1983 (48 FR 26720), FDA published proposed regulations governing the investigational new drug (IND) development process. This set of proposed regulations is commonly referred to as the IND Rewrite. These regulations cover the full range of the IND process, including the contents of IND applications, FDA procedures for reviewing IND's, meetings between FDA reviewers and drug sponsors, and reporting by sponsors of adverse drug reactions observed during clinical trials. The IND Rewrite proposal also addressed the conditions under which patients could obtain investigational drugs primarily for treatment use, and the conditions under which investigational drugs may be sold.

Elsewhere in this issue of the Federal Register, FDA is publishing a final rule addressing all portions of the IND Rewrite proposal, except for the provisions concerning treatment use and sale of investigational drugs, which are being reproposed here. Although FDA believes that it could justify publishing these provisions also as a final rule at this time, due to the increasing public interest in the availability of investigational drugs for treatment use, and in an abundance of caution, the agency is providing an additional opportunity for public comment. FDA is providing 30 days for public comment. FDA believes that the compelling public health advantages to be gained from issuing a final rule as quickly as possible constitute good cause under 21 CFR 10.40(b)(2) for providing less than the normal 60 day comment period. The agency plans to issue a final rule by May 18, 1987. FDA is proposing that any final rule based on this proposal be effective 30 days after the date of its publication in the Federal Register.

I. Contents of the Reproposal

FDA is reproposing 21 CFR 312.34 (Treatment use of an investigational new drug) and 21 CFR 312.7(d) (Sale of an investigational drug). These provisions, as reproposed, are summarized as follows:

Treatment Use

Under the reproposal, treatment use of an investigational drug would be permitted where the drug is intended to treat an immediately life-threatening or otherwise serious disease; there is no satisfactory alternative drug or other therapy available to treat the disease; the drug is under investigation in a

controlled clinical trial under an IND in effect for the trial; and the sponsor of the controlled clinical trial is pursuing marketing approval of the investigational drug with due diligence.

The reproposal also provides two additional sets of criteria, depending upon whether the drug is intended to treat an immediately life-threatening disease or a disease that is serious but not immediately life-threatening. In the case of a "serious" disease, the reproposal provides that the Commissioner may deny a request for treatment use if he or she finds there is insufficient evidence of safety and effectiveness to support such use. In contrast, under the reproposal, for a drug intended to treat an "immediately life-threatening" disease, the Commissioner may deny a request for treatment use if he or she finds that, on the basis of clinical data or other reliable scientific evidence in the IND file, the drug clearly does not provide a therapeutic benefit; or the drug would expose the patients to whom the drug is to be administered to an unreasonable and significant additional risk of illness or injury. The reproposal also adds conforming amendments to the clinical hold section of the regulation.

Sale

The reproposal presents two distinct contexts for the sale of an investigational drug: First, during a clinical trial; and second, under a treatment protocol/IND. Under a reproposal, for sale of an investigational drug during a clinical trial, prior FDA approval is required, and such approval would be granted only upon a showing that sale is needed for the sponsor to undertake or continue the clinical trial. In contrast, the reproposal would authorize sponsors to charge for investigational drugs made available to patients under a treatment protocol/IND, so long as the sponsor complies with certain designated safeguards against commercialization and notifies FDA 10 days prior to the commencement of such sale. Prior FDA approval of the sale in this context would not be required.

The reproposal also contains a provision allowing FDA to withdraw authorization for sale if the price charged is manifestly unfair or if the conditions underlying the initial authorization for sale are no longer satisfied.

These repropored provisions on treatment use and sale are discussed further below in conjunction with public comments submitted in response to the June 9, 1983, proposal.

II. Response to Comments

A. Treatment Use of Investigational Drugs

1. One comment contended FDA did not have legal authority to permit the use of investigational drugs for treatment and in emergencies. The comment asserted that such uses were inconsistent with the grant of statutory authority in section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) allowing FDA to exempt from the otherwise applicable provisions of the law new drugs intended "solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs."

In allowing for the use of investigational drugs for treatment, FDA is officially recognizing in its regulation longstanding agency practice. FDA believes the comment too narrowly construes the statutory language in section 505(i) of the act. Section 505(i) of the act gives FDA broad discretionary authority to promulgate regulations governing the clinical investigation of new drugs to protect the rights, safety, and welfare of human subjects and otherwise to promote the public health. In implementing this grant of authority, FDA has properly responded to a demand from health professionals to permit limited use of investigational drugs to treat diseases for which there are no satisfactory alternative treatments. The agency believes that the treatment IND/protocol provision, as would be codified under this reproposal, appropriately balances the requirement that use of a drug under section 505(i) of the act be investigational with the public demand for some treatment of promising investigational drugs, and is clearly consistent with the public health mandate of the statute.

The requirement for a treatment IND/protocol calls for the submission of information in advance of treatment for the protection of subjects, and for the submission of safety reports and other information following administration of the drug that provide information on matters concerning the drug's safety and efficacy. Thus, FDA believes that there is a sufficient investigational aspect to these treatment uses to justify agency authorization of such uses.

The language of section 505(i) of the act, in the agency's view, is intended to ensure that unapproved new drugs are not commercialized before marketing approval, and not to prohibit some use of an investigational drug in a "hybrid" treatment-investigational setting. To read the language as prohibiting absolutely the use of an investigational

drug for treatment might also call into question agency authorization of a large fraction of studies, most of which also have both an investigational and a treatment purpose. Given the clear intent of the statute that marketing approvals be based on data obtained from such studies, that result could not have been intended.

Finally, FDA notes that the legislative history of the new drug provisions demonstrates that Congress intended to encourage FDA to make promising investigational drugs available to seriously ill patients who are not treatable with alternative therapies. For example, Congress, in enacting in January 1983 the Orphan Drug Amendments (Pub. L. 97-41) to the Federal Food, Drug, and Cosmetic Act, clearly assumed the existence of treatment use for investigational drugs. As seen in section 528, the act instructs the Secretary of Health and Human Services (and, by delegation, FDA) to encourage sponsors of orphan drugs to make their drugs available under treatment protocols, i.e., "to design protocols for clinical investigations of the drug which may be conducted under the [IND] to permit the addition to the investigations of persons with the disease or condition who need the drug to treat the disease or condition and who cannot be satisfactorily treated by available alternative drugs." This statute fully supports the existence of and need for procedures that will permit some seriously ill persons to be treated with investigational drugs.

2. Many comments discussed the proposed criteria that FDA would use in determining whether to authorize use of an investigational drug for treatment. Several comments recommended alternative criteria to those proposed. One comment contended that the proposed criteria were simply too vague. Another comment indicated that FDA should accept the assessment of need for the drug by the patient's personal physician as sufficient justification for allowing treatment use. Another comment contended that if the proposed criteria were met, an investigational drug would satisfy the conditions for marketing approval, thus obviating the need for further studies. Another comment suggested that in determining whether there is sufficient evidence of a drug's safety and effectiveness to justify its proposed use, FDA should clarify that the only sort of evidence deemed "sufficient" would be evidence derived from controlled studies.

As discussed in the preamble of the proposed rule, an important goal of treatment protocols/IND's is to provide promising new drugs to patients with

serious disease conditions for which there are no alternative therapies. This reproposal, like the proposed rule, is intended to improve physician (and patient) access to these investigational drugs by expressly authorizing the practice in regulations and clarifying what steps are necessary to obtain an investigational drug for treatment use. The treatment use program would protect against both the commercialization of investigational drugs, prior to marketing approval, and the use of investigational drugs for disease conditions that either are not serious or immediately life-threatening or for which there are alternative therapies. By restricting treatment use to serious and immediately life-threatening disease conditions and specifying what criteria must be met for treatment use for each, the program fulfills FDA's responsibility to protect the rights, safety, and welfare of human subjects and otherwise to promote the public health. The criteria for such use represent a significant improvement over previous, unwritten guidelines in specifically identifying the universe of eligible drugs and establishing reasonable guidelines for agency action.

FDA does not agree that criteria either significantly more stringent or more relaxed would adequately meet the need for a treatment use program. Significantly more stringent criteria for immediately life-threatening diseases, such as proof of a drug's safety and effectiveness, which can only be developed near the end of the investigational process, would not serve the purpose of allowing treatment use at an earlier stage than that provided by commercially approved drugs. Requiring a degree of proof only slightly less than is necessary for general market distribution would unnecessarily restrict a drug that could provide real benefits in the particular case under treatment.

On the other hand, where a disease is not serious or immediately life-threatening or there is insufficient evidence of safety and effectiveness, allowing a drug to be used for treatment would allow use that is too widespread given the lack of knowledge about the benefits and safety of the drug. Thus, the need for a treatment use program to bring promising new drugs to patients who particularly need them calls for standards designed to achieve the goal, such as those contained in this reproposal, of safety and therapeutic benefit for a specific category of patients.

FDA agrees that the criteria, as originally proposed, were in some respects overly general or too vague,

and that it is appropriate to provide more specific guidance, where possible, on the circumstances under which treatment use would be allowed. Consequently, the criteria provision in the reproposal is more specific and elaborates on the proposed provision by breaking out two cases of disease conditions that warrant distinction and specifying the criteria appropriate to each. The two cases are those in which the disease is immediately life-threatening and those in which the disease is serious, but not immediately life-threatening. This distinction is made because the consequences of denying treatment use for a patient in an immediately life-threatening situation are much graver than for a patient with a serious, but not immediately life-threatening condition. The criteria to deny treatment use for an immediately life-threatening disease, in turn, recognize this distinction by specifying that denial of treatment use must be predicated on evidence that the drug clearly does not provide a therapeutic benefit or the drug would present an unreasonable and significant additional risk of illness or injury. On the other hand, the denial of treatment use for serious, but not immediately life-threatening, disease conditions can be based on a finding of insufficient evidence of safety and effectiveness to support such use. However, in both cases, there must be no satisfactory alternative drug or therapy available.

What constitutes an immediately life-threatening illness cannot be rigorously defined. The medical judgment of the sponsor or treating physician must carry considerable weight in deciding whether an illness poses a sufficient threat to justify treating patients with a drug for which safety or effectiveness has not been demonstrated fully. Generally, an immediately life-threatening illness is one that poses a significant threat of the patient's dying unless the course of the disease is promptly altered to reduce that possibility. As used in this context, the term "immediately" refers to the need to treat the illness quickly, without implying any particular time within which death is expected to occur (though such time is expected to be reasonably short). The term "life-threatening" extends both to situations in which it is certain that a patient's disease will result in death and to situations in which death is a highly probable outcome of the disease.

For all treatment IND's, the reproposal clarifies that the drug must be under IND investigation in a controlled clinical trial, and that the sponsor is pursuing marketing approval with due diligence.

These provisions are designed to ensure there is no incentive to prolong the investigational status of a drug subject to treatment IND, especially where the drug is to be sold to patients under § 312.7(d), as reposed. The term "due diligence" is intended to refer to an applicant's good faith effort to seek timely and expeditious marketing approval through action meant to advance the progress of the IND or subsequent marketing application.

FDA disagrees with the comment that a physician's assessment alone should be sufficient justification for allowing treatment. The final rule relies heavily on the joint assessment of the physician and sponsor; however, FDA's statutory responsibility necessitates that it retain authority to review the appropriateness of IND treatment use and to ensure that such use does not constitute the commercialization of an investigational drug.

FDA disagrees with the notion that a drug that meets the criteria in § 312.34(b) would also meet the requirements for marketing approval. The regulation requires that the sponsor submit sufficient evidence of a drug's safety and effectiveness to justify its treatment use for serious disease conditions, but does not demand that the sponsor submit the same definitive, statutorily sufficient evidence of a drug's safety and effectiveness required for NDA approval. Thus, a sponsor could satisfy the criteria for treatment IND authorization by presenting evidence that is supportive of a drug's effectiveness for its treatment use, yet not meet the statutory standard of effectiveness, i.e., substantial evidence consisting of adequate and well-controlled clinical investigations, or the statutory standard for safety, required for open marketing of the drug under the New Drug Approval process. In the case of treatment use for immediately life-threatening diseases, the evidence may not even be sufficient to meet the standard for treatment use of a serious disease.

With respect to the comment suggesting that only evidence from controlled studies be used in determining whether there is sufficient evidence of a drug's safety and effectiveness to justify its proposed use, FDA advises that it will rely on all data available at the time the request for treatment use is received by the agency.

In the case of a drug for a life-threatening illness, for example, it is expected that data from controlled clinical trials will ordinarily be available at the time a treatment IND is requested. Even so, there may be

circumstances where little data are available concerning the therapeutic benefit of a drug, particularly if Phase 1 studies have just ended or Phase 2 testing has only recently begun. In the case of an immediately life-threatening disease for which there is no adequate therapy available, the reproposal requires that the Commissioner have adequate support for a determination that there is an unreasonable and additional risk or clearly no therapeutic benefit in order for the Commissioner to deny treatment use. In making such a determination, the Commissioner obviously must have sufficient information, and must make use of all available information. It follows that, under the reproposal, it is expected that the Commissioner will be provided with sufficient data to make the specified determination. Once treatment use has been authorized, in the circumstance in which additional data later become available to provide a basis for the Commissioner to determine that the drug either clearly has no therapeutic benefit or presents an unreasonable and significant additional risk, the Commissioner may proceed under reproposal § 312.42(b)(3) to place the treatment IND on clinical hold.

Finally, agency experience has shown that patients are served most efficiently if the treating physician requesting an investigational drug for treatment use works through the sponsoring pharmaceutical company (under a treatment protocol to an existing IND) rather than applying directly to FDA for a separate treatment IND. Accordingly, although the reproposal contains procedures for either route, the treating physician would be required first to attempt obtaining the drug from the IND sponsor under a treatment protocol before submitting a separate treatment IND to FDA.

3. One comment expressed concern about FDA's stated willingness under certain circumstances to waive IRB review of treatment IND's and treatment protocols. Noting that review of the adequacy of informed consent is one function of the IRB, the comment wondered whether, if FDA finds that IRB review of a treatment use is unnecessary for the protection of subjects, the investigator would still be required to obtain his or her subject's informed consent. In addition, several other comments asserted that IRB review was necessary for the protection of both the patient and investigator and that no alternative method of assuring patient protection would provide adequate incentives to real patient protection. In contrast, one comment

suggested that all treatment uses should be granted a "blanket" exemption from IRB review requirements.

FDA emphasizes that it will only waive IRB review if it finds that there are adequate alternative means of assuring the protection of subjects' safety, welfare, and rights. In the proposal, FDA stated that it might on its own initiative waive IRB review because the agency believes that in the treatment IND/protocol context there may frequently be adequate alternative guarantees of subject protection. These guarantees include the required findings FDA must make in authorizing a treatment IND/protocol, that the necessary evidence is available to support the proposed treatment use, and that the potential risks of the drug are commensurate with the seriousness of the patient's disease. All of these findings are analogous to findings that an IRB is required to make. In addition, given that the physician's primary goal in using an investigational drug under a treatment IND or protocol is to provide the best available therapy to an individual patient, there is less likelihood than in a conventional investigation that concerns about the patient will be subordinated to concerns about the investigation. The less likelihood that a subject's interest may be subordinated, the less need there may be for a neutral, objective, third party to oversee the investigation. Finally, FDA will insist on assurances that adequate informed consent is obtained, regardless of whether IRB review is obtained or waived. The requirement for informed consent is independent of the requirement for IRB review and is not subject to waiver except in extraordinarily unusual circumstances. These factors lead FDA to conclude that waiver of IRB review of treatment IND's/protocol may frequently be warranted.

4. Proposed § 312.34(c) [reproposed as § 312.35(b)] provides that the supplying of an investigational drug to a licensed medical practitioner by a sponsor of a separate clinical investigation shall be deemed to authorize the incorporation-by-reference of the technical information contained in the supplying sponsor's IND into the medical practitioner's IND. One comment argued that, given the confidentiality of much of the information in an IND and the often highly competitive nature of new drug development, it would be inappropriate not to insist that authorization for incorporation be affirmatively documented by a letter from the sponsor. Another comment claimed that the sponsor should always be the party

to control information to be referenced by another party. This comment claimed that there is no mechanism whereby FDA can verify the source of an investigational drug that may also be commercially available for other therapeutic uses. In contrast, one comment approved of the "deemed incorporated" provision, but concluded that the provision was deficient in failing to give the consignee-physician access to pertinent information in the commercial sponsor's IND file. The comment urged that the final rule ensure that the treating physician have access to all information in the commercial sponsor's IND that may be relevant to the treatment use of the drug. The comment claimed that a policy permitting nondisclosure would enable a commercial sponsor to withhold negative information about its drug from the physician and would, therefore, be incompatible with the physician's proper treatment of the patient and with the right of the patient to be fully informed.

FDA calls attention to the fact that, under the reproposal, most physician access to investigational drugs for treatment use would come through the sponsor. In the infrequent event that the physician is directly applying for a treatment IND, FDA believes it appropriate to consider a commercial drug firm that chooses to supply its investigational drug to a physician-sponsor to have consented to the information in the drug firm's IND being consulted by FDA in assessing the physician's IND. It is essential that FDA have access to this information in its review of the physician's treatment IND submission. The comments, however, misunderstand the significance of the "deemed incorporated" provision. First, it should be emphasized that the provision would not compromise the confidentiality of commercially valuable information in the drug firm's IND as the information incorporated-by-reference would be available solely to FDA for its review. The provision does not authorize disclosure of the incorporated information to the physician or to any third party. Second, if a drug firm remains concerned about the potential implications of the provision, the firm can either choose not to provide the drug to the physician, or preferably can choose to accommodate the physician's request for treatment use of the drug under a company developed treatment protocol.

As the treatment IND provisions are only available for unmarketed drugs, FDA can with some confidence assume that an investigational drug in the treating physician's possession was

shipped from a drug firm that holds a commercial IND on the drug. Therefore, FDA believes that it should be able to "verify" the source of a drug.

Finally, with respect to the request that the physician-consignee be given access to the information on the investigational drug, the agency expects the supplying drug company to provide the physician with a copy of the same investigator brochure that it gives its own investigators. The brochure, which contains a summary of all information relevant to the investigational use of the drug, should be adequate to ensure the drug's proper use by the physician. The agency believes that individual treating physicians should no more need access to the technical information in the drug firm's IND than would investigators conducting controlled studies for the sponsor under that IND.

5. One comment urged that a physician who obtains an investigational drug under a treatment IND be required to relay important safety information obtained during the treatment use to the drug company that supplied the drug.

First, it should be emphasized that individual physician-sponsors of treatment IND's are, like sponsors of commercial IND's, required to submit safety reports to FDA in accordance with § 312.32. FDA also strongly encourages a physician who obtains drugs under his or her own treatment IND's to provide such safety information to the drug company that supplies the physician with the investigational drug. However, FDA does not believe it practical to require such concurrent reporting of safety information. The fact that some physicians may not provide such information to their drug firm suppliers is one reason why the agency would prefer a drug firm with a drug eligible for treatment use under § 312.34 to make the drug available under its own treatment protocol. Use of treatment protocols increases the likelihood that useful safety information generated by the treatment use will be properly collected, interpreted, and forwarded to the sponsor and FDA.

6. One comment urged that FDA list the information required to support a treatment protocol.

FDA advises that the information required to support a treatment protocol is that listed in § 312.35(a)—essentially a copy of the protocol itself and a copy of the brochure to be given each treating physician. Most, if not all, other information supporting the treatment protocol should already be in the drug firm's commercial IND and may be incorporated-by-reference.

B. Sale of Investigational Drugs

7. Many comments objected to the proposed change to the policy on sale of investigational drugs. Under the proposed policy, sale would not be allowed except upon the written approval of the Director of the Center for Drugs and Biologics. One comment claimed that there was no statutory authority for FDA to become involved in matters relating to the sale of investigational drugs. The comment maintained that current FDA requirements on sale have worked well and urged FDA to retain those requirements. Another comment, while not specifically objecting to the proposed policy, urged that the final rule require FDA to respond to a sponsor's request within a specified time limit. One comment urged the adoption of a very stringent standard for determining whether the sale of an investigational drug would be appropriate. Conversely, another comment suggested the sale be routinely allowed so long as the proposed sale price was not greater than necessary to recover costs of manufacture, research, development, and handling.

The agency disagrees with the comment claiming it does not have statutory authority. In the case of drugs subject to the Public Health Service Act, the authority for regulating the sale of an investigational biological drug is clear. Under section 351 of the Public Health Service Act (42 U.S.C. 262), no person may "sell, barter, or exchange, or offer for sale" a biologic drug product unless the product is subject to a biological product license. In the case of drugs that are not biological products, and thus subject to the new drug provisions of the Federal Food, Drug, and Cosmetic Act, the authority for regulating the sale of such investigational drugs is equally clear. Under the Federal Food, Drug, and Cosmetic Act, the Secretary of Health and Human Services (and, by delegation, FDA) has the responsibility for promulgating regulations to exempt from the otherwise applicable statutory provisions governing the shipment of new drugs, "drugs intended solely for investigational use * * *." In the agency's view, the sale of drugs under most circumstances, whether it be by a sponsor or investigator, suggests that it is being commercialized, a practice that is presumptively inconsistent with the drug's use solely for investigational purposes. Therefore, the agency believes that it is reasonable and within its statutory authority to prohibit a sale of an investigational drug unless it can be demonstrated that the proposed sale is

consistent with the drug's investigational status and does not commercialize the drug prior to its approval.

The agency notes that this policy on sale and the general prohibition against commercialization are not policies newly adopted in the IND Rewrite rulemaking, but have been part of the IND regulations since 1963. FDA believes, however, that if sale were not permitted when appropriate, research and development in the drug industry and the medical field might be curtailed, in turn unnecessarily delaying or eliminating certain improvements in health care. Prohibitive costs would become a disincentive to new drug development if the sponsors did not have adequate assurance that sale is permitted when warranted.

The reproposal, like the proposal, prohibits the following: promotion of an investigational new drug; commercial distribution of an investigational new drug; and prolonging an investigation. The reproposal adds a provision that allows FDA to withdraw the sale authorization if the price being charged for an IND is manifestly unfair or the drug is promoted or otherwise commercialized. FDA believes this added provision is necessary to protect against abuses of sale authorization that might arise when the drug is the only treatment or therapy available.

As proposed, the authority to approve sale of investigational drugs for clinical trials belonged exclusively to the Director, Center for Drugs and Biologics. On reconsideration, FDA has revised the rule to authorize the directors of the review offices to approve sale requests in place of the Director.

As noted above, one comment suggested that FDA should specify a time frame in which responses to sale requests would be made. The procedure in the proposed rule for all investigational new drugs required application and written approval by FDA. In this reproposal, in the case of sale of a drug intended for treatment use, notification by the sponsor is required and after 10 days sale would be allowed unless FDA disapproves. For clinical trial sale requests, as in the proposed rule, sale would be allowed only after FDA approves sale. This distinction is justified for two reasons. First, affirmative approval would unnecessarily delay the availability of treatment use drugs that have met the criteria for treatment use. Second, the costs of IND's for clinical trials are standard costs of doing business while costs of treatment use drugs will be

costs incurred beyond those needed to obtain marketing approval.

The cost of a drug used in clinical studies is normally absorbed by the sponsor as a cost of doing business. This is because clinical studies are required to obtain marketing approval from FDA, and because such studies might be undertaken even if FDA approval were not required. The traditional notion that clinical trial costs are a cost of doing business should hold unless the sponsor provides adequate explanation for the sale and receives affirmative FDA approval. For example, an explanation of specific modern advances in science and technology that create an environment of extremely high costs could warrant the sale of drugs used in clinical trials. In addition, permitting sale in such cases should permit greater competition in drug development by permitting small and fledgling companies to test products that are extremely expensive to produce, providing all ethical concerns are met.

In light of this greater justification burden, i.e., demonstrating why the costs should not be absorbed as a cost of doing business, FDA does not believe it should commit to respond to requests for sale of drugs in clinical trials within a specified time frame. Nevertheless, FDA is committed to expediting review of these requests within the constraints imposed by available resources and other priorities.

However, in the case of sale for treatment use, if both an attending physician and the relevant sponsor conclude that an investigational drug should be made available for treatment and such drug meets the treatment use criteria in § 312.34(b), it would be detrimental to disallow or delay the sale of the drug. There might be no incentive for a sponsor to supply investigational drugs for treatment use, thus denying the drug to patients who, in the exercise of their informed judgment, choose to avail themselves of this treatment. Similarly, any delay in the authorization of sale could cause a delay in the availability of the drug that would be inappropriate in light of the circumstances, i.e., a serious or immediately life-threatening disease condition for which there is no alternative therapy.

Although sale would be allowed under specified conditions in this reproposal, it would be inappropriate to introduce into the sale provision specific price controls or a procedure in which the agency becomes a price regulator. The sponsor is in the best position to know the costs involved in the manufacturing of a drug. However, there

is a potential that undue advantage may be taken of seriously or terminally ill patients, particularly due to the absence of alternative treatments, by charging exorbitant prices. Accordingly, to curb any possible abuse, under the reproposal FDA could withdraw authorization for sale of a drug, distributed under either a clinical trial or a treatment IND, if it determines that a charge for the drug is manifestly unfair.

In summary, the sale provision in the reproposal does not unduly restrict sale nor does it allow unrestricted sale. In all instances of investigational drug sale, the prohibitions against promotion and commercialization still apply. In addition, FDA has the authority to withdraw sale authorization if any abuses occur, including promotion and commercialization. FDA believes the policy as set forth in this reproposal would appropriately provide for sale when the circumstances of a particular investigational drug so warrant.

8. One comment asked that the sale provisions be clarified to assure that FDA does not regulate hospital charges imposed for the costs of handling, storing, and administering investigational drug products.

The sale provisions pertain to the direct sale of the drug itself, not to incidental charges imposed for services ancillary to the distribution or administration of the drug. Thus, the provision does not apply to charges imposed by hospital pharmacies for handling investigational drug products.

9. One comment suggested that if a physician wants to conduct an independent investigation under a treatment IND, the firm supplying the physician the drug should be permitted to charge the physician for the product. On the other hand, another comment, believing that FDA policy already allowed firms to sell products to physicians sponsoring treatment IND's, argued against that policy by suggesting that permitting sale of an investigational drug reduces the commercial sponsor's incentives to do the necessary work to prepare a marketing application.

When a commercial firm ships an investigational drug to a treating physician for use under the physician's treatment IND, the commercial firm may make reasonable charges for the drug in accordance with the specific provisions of § 312.7(d). It should be noted that the supplier is still subject to the general prohibitions in § 312.7(b) against commercializing an unapproved investigational drug, and any sale of the drug by the firm would be examined in that context.

III. Economic Impact

The agency has examined the economic impact of this proposed rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96-354). These proposed procedures would facilitate the availability of promising new drugs to patients who need treatment. The proposed revisions would also modify conditions under which investigational drugs may be sold. Generally, these revisions would have a favorable impact on drug sponsors, investigators, physicians, and patients, while adequately protecting the safety of human subjects.

The proposed procedures would expedite public access to certain promising new drugs. For consumers, these new procedures would make many drugs for immediately life-threatening and other serious diseases more widely and quickly available than occur under existing regulations. These procedures would also benefit treating physicians because the drug sponsor would normally file the necessary paperwork to FDA for them. Finally, these procedures would benefit sponsors of unusually expensive drugs and/or sponsors whose size and resources make it difficult to finance new drug development. Under the reproposal, such companies would be able to recover some of their expenses for research sooner than is possible under current regulations. Therefore, the agency certifies that this proposed rule, if promulgated, will not have a significant economic impact on small entities as defined by the Regulatory Flexibility Act.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1980

Sections 312.7 and 312.35 of this proposed rule contain collection of information requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of these collection of information requirements. Other organizations and individuals desir-

ing to submit comments on the collection of information requirements should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, Rm. 3208, New Executive Office Building, Washington, DC 20503. Attn: Desk Officer for FDA.

Interested persons, may, on or before April 20, 1987, submit to the Dockets Management Branch [HFA-305], Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this reproposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 312

Drugs, Medical research.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, it is proposed that Part 312 be amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for 21 CFR Part 312 continues to read as follows:

Authority: Secs. 501, 502, 503, 505, 506, 507, 701, 52 Stat. 1049-1053 as amended, 1055-1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended [21 U.S.C. 351, 353, 355, 356, 357, 371]; sec. 351, 58 Stat. 702 as amended [42 U.S.C. 262]; 21 CFR 5.10, 5.11.

2. In § 312.7 by revising paragraph (d) to read as follows:

§ 312.7 Promotion and Sale of Investigational Drugs

* * * * *

(d) *Sale of an investigational drug—* (1) *Clinical trials under an IND.* Sale of an investigational drug in a clinical trial under an IND is not permitted without prior written approval of the Director of the Center for Drugs and Biologics, the Director of the Office of Drug Research and Review, or the Director of the Office of Biologics Research and Review, as the case may be, upon a full written explanation by the sponsor that sale is required in order for the sponsor to undertake or continue the clinical trial.

(2) *Treatment protocol or treatment IND.* A sponsor or investigator may sell an investigational drug for a treatment use under a treatment protocol or treatment IND that is in effect for the treatment use provided (i) the sale does not constitute commercial marketing of

a new drug for which a marketing application has not been approved; (ii) the drug is not being commercially promoted or advertised; and (iii) the sponsor of the drug is actively pursuing clinical studies and marketing approval with due diligence. FDA must be notified in writing, in an information amendment submitted under § 312.31, 10 days prior to the commencement of sale of such a drug. Prior approval of the sale by FDA is not required.

(3) *Withdrawal of authorization for sale.* (i) If FDA determines that the price charged for an investigational drug authorized to be sold is manifestly unfair, FDA may withdraw authorization for the sale of the drug until the price is reduced or the charge eliminated.

(ii) Authorization to sell an investigational drug under paragraph (d) (1) or (2) of this section may be withdrawn by FDA if the agency finds that the conditions underlying the authorization are no longer satisfied.

3. By adding § 312.34 to read as follows:

§ 312.34 Treatment use of an investigational new drug.

(a) *General.* A drug that is not approved for marketing may be under clinical investigation for an immediately life-threatening or other serious disease condition in patients for whom no satisfactory alternative drug or other therapy is available. During the clinical investigation of the drug, it may be appropriate to use the drug in the treatment of patients not in the clinical trials, in accordance with a treatment protocol. Ordinarily, in the case of a serious disease, a drug may be made available for treatment under this section after Phase 2 investigations have been completed; however, in the case of an immediately life-threatening disease, or in other appropriate circumstances, FDA may permit such use earlier in the investigational process. Administration of an investigational drug under this section serves both to provide treatment and the investigational purpose of gathering additional data on the drug's safety and effectiveness. For purposes of this section, the "treatment use" of a drug includes the investigational use of a drug for diagnostic purposes.

(b) *Criteria.* (1) FDA shall permit an investigational drug to be used for a treatment use under a treatment protocol or treatment IND if:

(i) The drug is intended to treat a serious or immediately life-threatening disease;

(ii) There is no satisfactory alternative drug or other therapy available to treat the disease;

(iii) The drug is under investigation in a controlled clinical trial under an IND in effect for the trial; and

(iv) The sponsor of the controlled clinical trial is pursuing marketing approval of the investigational drug with due diligence.

(2) *Serious disease.* For a drug intended to treat a serious disease, the Commissioner may deny a request for treatment use under a treatment protocol or treatment IND if he or she finds there is insufficient evidence of safety and effectiveness to support such use.

(3) *Immediately life-threatening disease.* For a drug intended to treat an immediately life-threatening disease, the Commissioner may deny a request for treatment use of an investigational drug under a treatment protocol or treatment IND if he or she finds that:

(i) On the basis of clinical data or other reliable scientific evidence in the IND file, the drug clearly does not provide a therapeutic benefit; or

(ii) The drug would expose the patients to whom the drug is to be administered to an unreasonable and significant additional risk of illness or injury.

(c) *Clinical hold.* FDA may place on clinical hold a proposed or ongoing treatment protocol or treatment IND in accordance with § 312.42.

4. By adding § 312.35 to read as follows:

§ 312.35 Submissions for treatment use.

(a) *Treatment protocol submitted by IND sponsor.* A sponsor of a clinical investigation of a drug who intends to sponsor a treatment use for the drug under § 312.34 shall submit to FDA a treatment protocol. A treatment use under a treatment protocol may begin 30 days after FDA receives the protocol or on earlier notification by FDA that the treatment use described in the protocol may begin.

(1) A treatment protocol is required to contain the following:

(i) The intended use of the drug.

(ii) An explanation of the rationale for use of the drug, including, as appropriate, either a list of what available regimens ordinarily should be tried before using the investigational drug or an explanation of why the use of the investigational drug is preferable to the use of available marketed treatments.

(iii) A brief description of the criteria for patient selection.

(iv) The method of administration of the drug and the dosages.

(v) A description of clinical procedures, laboratory tests, or other

measures to monitor the effects of the drug and to minimize risk.

(2) A treatment protocol is to be supported by the following:

(i) Informational brochure for supplying to each treating physician.

(ii) The technical information that is relevant to safety and effectiveness of the drug for the intended treatment purpose. Information contained in the sponsor's IND may be incorporated by reference.

(iii) If a waiver from IRB review and approval requirements is desired, a request for the waiver. (FDA may on its own initiative waive IRB review requirements under Part 56, if it finds such review unnecessary for the protection of subjects to be treated.)

(b) *Treatment IND submitted by licensed practitioner.* (1) If a licensed medical practitioner wants to obtain an investigational drug subject to a controlled clinical trial for a treatment use, the practitioner should first attempt to obtain the drug from the sponsor of the controlled trial under a treatment protocol. If the sponsor of the controlled clinical investigation of the drug will not establish a treatment protocol for the drug under paragraph (a) of this section, the licensed medical practitioner may seek to obtain the drug from the sponsor and submit a treatment IND to FDA requesting authorization to use the investigational drug for treatment use. A treatment use under a treatment IND may begin 30 days after FDA receives the IND or on earlier notification by FDA that the treatment use under the IND may begin. A treatment IND is required to contain the following:

(i) A cover sheet (Form FDA-1571) meeting § 312.23(g)(1).

(ii) Information (when not provided by the sponsor) on the drug's chemistry, manufacturing, and controls, and prior clinical and nonclinical experience with the drug submitted in accordance with § 312.23. A sponsor of a clinical investigation subject to an IND who supplies an investigational drug to a licensed medical practitioner for purposes of a separate treatment clinical investigation shall be deemed to authorize the incorporation-by-reference of the technical information contained in the sponsor's IND into the medical practitioner's treatment IND.

(iii) A statement of the steps taken by the practitioner to obtain the drug under a treatment protocol from the drug sponsor.

(iv) A treatment protocol containing the same information listed in paragraph (a)(1) of this section.

(v) If a waiver from IRB review and approval requirements is desired, a

request for the waiver, as provided in paragraph (a)(2)(iii) of this section.

(vi) A statement of the practitioner's qualifications to use the investigational drug for the intended treatment use.

(vii) The practitioner's statement of familiarity with information on the drug's safety and effectiveness derived from previous clinical and nonclinical experience with the drug.

(viii) Agreement to report to FDA safety information in accordance with § 312.32.

(2) A licensed practitioner who submits a treatment IND under this section is the sponsor-investigator for such IND and is responsible for meeting all applicable sponsor and investigator responsibilities under this part and Parts 50 and 56.

5. In § 312.42 by adding paragraph (b)(3) to read as follows:

§ 312.42 Clinical holds and requests for modification.

(b) * * *

(3) *Clinical hold of a treatment IND or treatment protocol—(i) Proposed use.*

FDA may place a proposed treatment IND or treatment protocol on clinical hold if it is determined that:

(A) The pertinent criteria in § 312.34(b) for permitting the treatment use to begin are not satisfied; or

(B) The treatment protocol or treatment IND does not contain the information required under § 312.35(a) or (b) to make the specified determination under § 312.34(b).

(ii) *Ongoing use.* FDA may place an ongoing treatment protocol or treatment IND on clinical hold if it is determined that:

(A) There becomes available a satisfactory alternative drug or other therapy to treat the disease for which the investigational drug is being used;

(B) The investigational drug is not under investigation in a controlled clinical trial under an IND in effect for the trial, or a clinical study under the IND has been placed on clinical hold;

(C) The sponsor of the controlled clinical trial is not pursuing marketing approval with due diligence;

(D) If the treatment IND or treatment protocol is intended for a serious disease, there is insufficient evidence of safety and effectiveness to support such use; or

(E) If the treatment protocol or treatment IND was based on an immediately life-threatening disease:

(1) On the basis of clinical data or other reliable scientific evidence in the IND file, the drug clearly does not provide a therapeutic benefit; or

(2) The drug would expose the patients to whom the drug is to be administered to an unreasonable and significant additional risk of illness or injury.

* * * * *

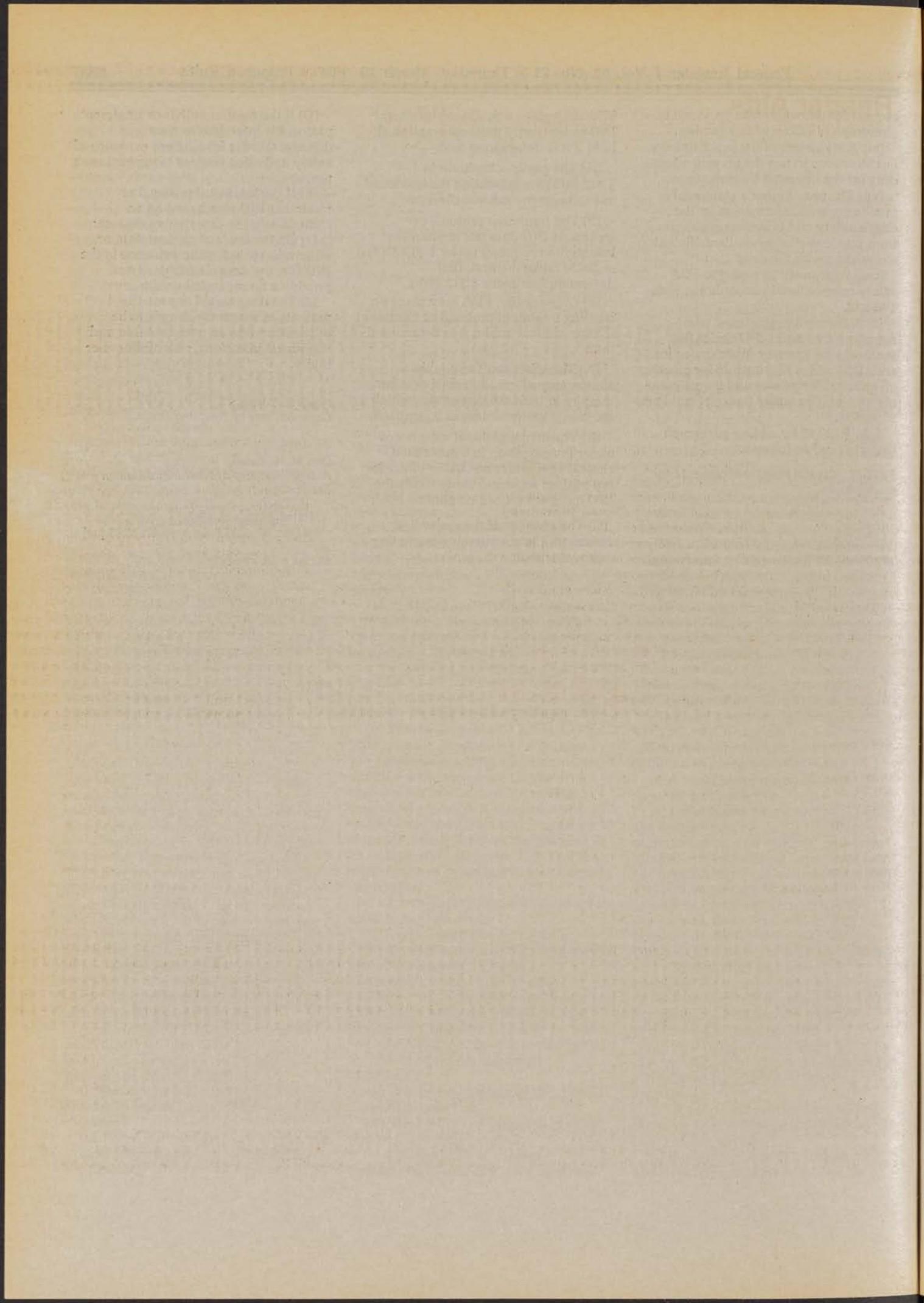
Frank E. Young.
Commissioner of Food and Drugs.

Don M. Newman.
Acting Secretary of Health and Human Services.

Dated: March 16, 1987.

[FR Doc. 87-6065 Filed 3-18-87; 12:05 pm]

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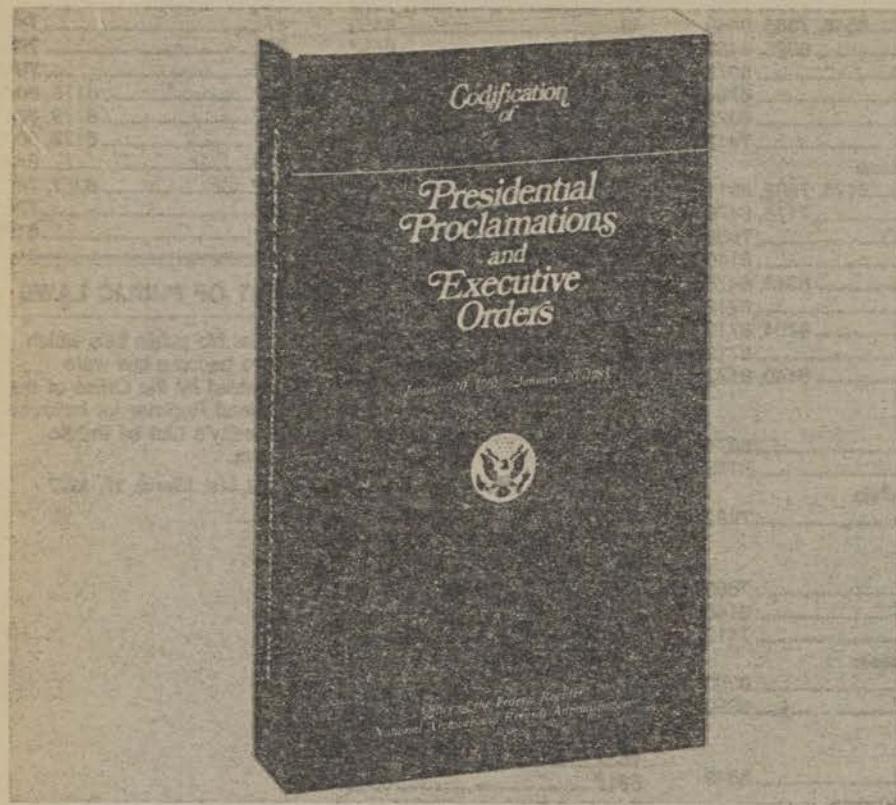
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